

HOUSE HEALTH AND HUMAN SERVICES COMMITTEE SUBSTITUTE FOR
HOUSE BILL 185

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

DISCUSSION DRAFT

AN ACT

RELATING TO HEALTH COVERAGE; AMENDING 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 MODIFY THE 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. Section 13-7-18 NMSA 1978 (being Laws 2018,
Chapter 9, Section 1) is amended to read:

"13-7-18. 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

underscoring material = new
[bracketed material] = delete

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. The group health plan shall include
14 in its evidence of coverage language describing an enrollee's
15 rights pursuant to this subsection.

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

24 G. A group health plan administrator's denial of a
25 request for an exception for step therapy protocols shall be

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1 subject to review and appeal pursuant to the Patient Protection
2 Act.

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

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

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

14 (2) 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 group health plan delivered, issued for delivery or~~
19 ~~renewed on or after January 1, 2019.~~

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

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

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1 (2) practice guidelines developed by the
 2 federal government or national or professional medical
 3 societies, boards or associations; or

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

11 SECTION 2. Section 27-2-12.23 NMSA 1978 (being Laws 2018,
 12 Chapter 9, Section 2) is amended to read:

13 "27-2-12.23. MEDICAL ASSISTANCE--PRESCRIPTION DRUG
 14 COVERAGE--STEP THERAPY PROTOCOLS--CLINICAL REVIEW CRITERIA--
 15 EXCEPTIONS.--

16 A. By January 1, 2019, the secretary shall require
 17 any medical assistance plan for which any step therapy
 18 protocols are required to establish clinical review criteria
 19 for those step therapy protocols. The clinical review criteria
 20 shall be based on clinical practice guidelines that:

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

24 (2) are developed and endorsed by an
 25 interdisciplinary panel of experts that manages conflicts of

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1 interest among the members of the panel of experts by:

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

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

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

14 (4) are created pursuant to an explicit and
15 transparent process that:

16 (a) minimizes bias and conflicts of
17 interest;

18 (b) explains the relationship between
19 treatment options and outcomes;

20 (c) rates the quality of the evidence
21 supporting recommendations; and

22 (d) considers relevant patient subgroups
23 and preferences; and

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

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1 B. In the absence of clinical guidelines that meet
2 the requirements of Subsection A of this section, peer-reviewed
3 publications may be substituted.

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

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

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

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1 patient;

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

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

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

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

22 (b) worsen a comorbid condition of the
23 patient; or

24 (c) decrease the patient's ability to
25 achieve or maintain reasonable functional ability in performing

1 daily activities.

2 E. Upon the granting of an exception to a medical
3 assistance plan's step therapy protocol, a medical assistance
4 plan shall authorize continuing coverage for the life of the
5 patient for the prescription drug that is the subject of the
6 exception request.

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

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

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

23 I. The provisions of this section shall not be
24 construed to prevent:

25 (1) a medical assistance plan from requiring a

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1 patient to try a generic equivalent of a prescription drug
2 before providing coverage for the equivalent brand-name
3 prescription drug; or

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

7 J. As used in this section, "medical necessity" or
8 "medically necessary" means health care services determined by
9 a practitioner, in consultation with the medical assistance
10 plan, to be 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 medical assistance plan
18 consistent with federal, national and professional practice
19 guidelines. These standards shall be applied to decisions
20 related to the diagnosis or direct care and treatment of a
21 physical or behavioral health condition, illness, injury or
22 disease."

23 SECTION 3. Section 59A-22-53.1 NMSA 1978 (being Laws
24 2018, Chapter 9, Section 3) is amended to read:

25 "59A-22-53.1. PRESCRIPTION DRUG COVERAGE--STEP THERAPY

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1 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

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

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

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

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

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

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

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1 (4) are created pursuant to an explicit and
2 transparent process that:

3 (a) minimizes bias and conflicts of
4 interest;

5 (b) explains the relationship between
6 treatment options and outcomes;

7 (c) rates the quality of the evidence
8 supporting recommendations; and

9 (d) considers relevant patient subgroups
10 and preferences; and

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

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

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

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1 accessible for insureds and practitioners on the insurer's
2 publicly accessible website.

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

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

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

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

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1 prescription drug that is the subject of the exception request
2 and that prescription drug was discontinued due to lack of
3 efficacy or effectiveness, diminished effect or an adverse
4 event; or

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

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

12 (b) worsen a comorbid condition of the
13 patient; or

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

17 E. Upon the granting of an exception to a health
18 insurance policy's, health care plan's or certificate of
19 insurance's step therapy protocol, an insurer shall authorize
20 coverage for the life of the insured for the prescription drug
21 that is the subject of the exception request. An insurer shall
22 include in its evidence of coverage language describing an
23 insured's rights pursuant to this subsection.

24 F. An insurer shall respond with its decision on an
25 insured's exception request within seventy-two hours of

1 receipt. In cases where exigent circumstances exist, an
2 insurer shall respond within twenty-four hours of receipt of
3 the exception request. In the event the insurer does not
4 respond to an exception request within the time frames required
5 pursuant to this subsection, the exception request shall be
6 granted.

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

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

15 I. The provisions of this section shall not be
16 construed to prevent:

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

22 (2) a practitioner from prescribing a
23 prescription drug that the practitioner has determined to be
24 medically necessary.

25 ~~[J. The provisions of this section shall apply only~~

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1 ~~to a health insurance policy, health care plan or certificate~~
2 ~~of insurance delivered, issued for delivery or renewed on or~~
3 ~~after January 1, 2019.~~

4 ~~K.]~~ J. The superintendent shall promulgate rules as
5 may be necessary to appropriately implement the provisions of
6 this section.

7 ~~[L.]~~ K. Nothing in this section shall be
8 interpreted to interfere with the superintendent's authority to
9 regulate prescription drug coverage benefits under other state
10 and federal law.

11 ~~[M.]~~ L. As used in this section, "medical
12 necessity" or "medically necessary" means health care services
13 determined by a practitioner, in consultation with the insurer,
14 to be appropriate or necessary, according to:

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

17 (2) practice guidelines developed by the
18 federal government or national or professional medical
19 societies, boards or associations; or

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

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

3 "59A-22B-8. PRIOR AUTHORIZATION FOR PRESCRIPTION DRUGS OR
4 STEP THERAPY FOR [~~SUBSTANCE USE DISORDER~~] CERTAIN CONDITIONS
5 PROHIBITED.--

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

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

20 **SECTION 5.** Section 59A-46-52.1 NMSA 1978 (being Laws
21 2018, Chapter 9, Section 5) is amended to read:

22 "59A-46-52.1. PRESCRIPTION DRUG COVERAGE--STEP THERAPY
23 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

24 A. Each individual or group health maintenance
25 organization contract delivered or issued for delivery in this

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1 state that provides a prescription drug benefit for which any
2 step therapy protocols are required shall establish clinical
3 review criteria for those step therapy protocols. The clinical
4 review criteria shall be based on clinical practice guidelines
5 that:

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

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

12 (a) requiring members to: 1) disclose
13 any potential conflicts of interest with carriers, insurers,
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
11 meet the requirements of Subsection A of this section, peer-
12 reviewed publications may be substituted.

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

25 D. A carrier shall expeditiously grant an exception

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

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

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

15 (3) while under the enrollee's current health
16 maintenance organization contract, or under the enrollee's
17 previous health coverage, the enrollee has tried the
18 prescription drug that is the subject of the exception request
19 or another prescription drug in the same pharmacologic class or
20 with the same mechanism of action as the prescription drug that
21 is the subject of the exception request and that prescription
22 drug was discontinued due to lack of efficacy or effectiveness,
23 diminished effect or an adverse 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 maintenance organization contract's step therapy protocol, a
13 carrier shall authorize coverage for the lifetime of the
14 enrollee for the prescription drug that is the subject of the
15 exception request. A carrier shall include in its evidence of
16 coverage language describing an enrollee's rights pursuant to
17 this subsection.

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

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

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

9 I. The provisions of this section shall not be
10 construed to prevent:

11 (1) a health maintenance organization contract
12 from requiring a patient to try a generic equivalent of a
13 prescription drug before providing coverage for the equivalent
14 brand-name prescription drug; or

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

18 ~~[J. The provisions of this section shall apply only~~
19 ~~to a health maintenance organization contract delivered, issued~~
20 ~~for delivery or renewed on or after January 1, 2019.~~

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

24 ~~[L.]~~ K. Nothing in this section shall be
25 interpreted to interfere with the superintendent's authority to

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

3 ~~[M.]~~ L. As used in this section, "medical
4 necessity" or "medically necessary" means health care services
5 determined by a practitioner, in consultation with the carrier,
6 to be 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 carrier 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.** Section 59A-47-47.1 NMSA 1978 (being Laws
19 2018, Chapter 9, Section 6) is amended to read:

20 "59A-47-47.1. PRESCRIPTION DRUG COVERAGE--STEP THERAPY
21 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

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

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1 criteria for those step therapy protocols. The clinical review
2 criteria shall be 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 health care plans,
11 insurers, health maintenance organizations, pharmaceutical
12 manufacturers, pharmacy benefits managers and any other
13 entities; and 2) recuse themselves if there is a conflict of
14 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 care plan restricts coverage of a
12 prescription drug for the treatment of any medical condition
13 through the use of a step therapy protocol, a subscriber and
14 the 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. A health care
17 plan may use its existing medical exceptions process in
18 accordance with the provisions of Subsections D through I of
19 this section to satisfy this requirement. The process shall be
20 made easily accessible for subscribers and practitioners on the
21 health care plan's publicly accessible website.

22 D. A health care plan shall expeditiously grant an
23 exception to the health care plan's step therapy protocol,
24 based on medical necessity and a clinically valid explanation
25 from the patient's prescribing practitioner as to why a drug on

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1 the health care plan's formulary that is therapeutically
2 equivalent to the prescribed drug should not be substituted for
3 the prescribed drug, if:

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

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

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

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

25 (a) cause a significant barrier to the

1 patient's adherence to or compliance with the patient's plan of
2 care;

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

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

8 E. Upon the granting of an exception to a health
9 care plan's step therapy protocol, a health care plan shall
10 authorize coverage for the lifetime of the subscriber for the
11 prescription drug that is the subject of the exception request.
12 A health care plan shall include in its evidence of coverage
13 language describing a subscriber's rights pursuant to this
14 subsection.

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

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

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

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

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

12 (2) a 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 health care plan delivered, issued for delivery or renewed~~
17 ~~on or after January 1, 2019.~~

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

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

25 ~~[M.]~~ L. As used in this section, "medical

1 necessity" or "medically necessary" means health care services
 2 determined by a practitioner, in consultation with the health
 3 care plan, to be appropriate or necessary, according to:

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

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

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

16 **SECTION 7. EXCEPTIONS.**--The provisions of Sections 1 and
 17 3 through 6 of this act do not apply to short-term plans
 18 subject to the Short-Term Health Plan and Excepted Benefit Act.

19 **SECTION 8. APPLICABILITY.**--The provisions of this act
 20 apply to group health insurance policies, health care plans or
 21 certificates of health insurance, other than small group health
 22 plans, that are delivered, issued for delivery or renewed in
 23 this state on or after January 1, 2025.