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

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

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

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 group health plan
4 administrators, insurers, health maintenance organizations,
5 health care plans, pharmaceutical manufacturers, pharmacy
6 benefits managers and any other entities; and 2) recuse
7 themselves if there is a 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
11 tables 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
23 subgroups and preferences; and

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

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

4 C. When a group health plan restricts coverage of
5 a prescription drug for the treatment of any medical
6 condition through the use of a step therapy protocol, an
7 enrollee 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 group health plan may use its existing
11 medical exceptions process in accordance with the provisions
12 of Subsections D through I of this section to satisfy this
13 requirement. The process shall be made easily accessible for
14 enrollees and practitioners on the group health plan's
15 publicly accessible website.

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

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

1 harm to the patient;

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

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

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

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

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

25 (c) decrease the patient's ability to

1 achieve or maintain reasonable functional ability in
2 performing daily activities.

3 E. Upon the granting of an exception to a group
4 health plan's step therapy protocol, the group health plan
5 administrator shall authorize continuing coverage for the
6 prescription drug that is the subject of the exception
7 request for no less than the duration of the therapeutic
8 effect of the drug. The group health plan shall include in
9 its evidence of coverage language describing an enrollee's
10 rights pursuant to this subsection.

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

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

23 H. After an enrollee has made an exception request
24 in accordance with the provisions of this section, a group
25 health plan shall authorize continued coverage of a

1 prescription drug that is the subject of the exception
2 request pending the determination of the exception request.

3 I. The provisions of this section shall not be
4 construed to prevent a:

5 (1) group health plan from requiring a
6 patient to try a biosimilar, interchangeable biologic or
7 generic equivalent of a prescription drug before providing
8 coverage for the equivalent brand-name prescription drug; or

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

12 J. As used in this section, "medical necessity" or
13 "medically necessary" means health care services determined
14 by a practitioner, in consultation with the group health plan
15 administrator, to be appropriate or necessary according to:

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

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

21 (3) any applicable clinical protocols or
22 practice guidelines developed by the group health plan
23 consistent with federal, national and professional practice
24 guidelines. These standards shall be applied to decisions
25 related to the diagnosis or direct care and treatment of a

1 physical or behavioral health condition, illness, injury or
2 disease."

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

5 "27-2-12.23. MEDICAL ASSISTANCE--PRESCRIPTION DRUG
6 COVERAGE--STEP THERAPY PROTOCOLS--CLINICAL REVIEW CRITERIA--
7 EXCEPTIONS.--

8 A. By January 1, 2019, the secretary shall require
9 any medical assistance plan for which any step therapy
10 protocols are required to establish clinical review criteria
11 for those step therapy protocols. The clinical review
12 criteria shall be based on clinical practice guidelines that:

13 (1) recommend that the prescription drugs
14 subject to step therapy protocols be taken in the specific
15 sequence required by the step therapy protocol;

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

19 (a) requiring members to: 1) disclose
20 any potential conflicts of interest with health care plans,
21 medical assistance plans, health maintenance organizations,
22 pharmaceutical manufacturers, pharmacy benefits managers and
23 any other entities; and 2) recuse themselves if there is a
24 conflict of interest; and

25 (b) using analytical and methodological SHPAC/SB 135
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1 experts to work to provide objectivity in data analysis and
2 ranking of evidence through the preparation of evidence
3 tables and facilitating consensus;

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

6 (4) are created pursuant to an explicit and
7 transparent process that:

8 (a) minimizes bias and conflicts of
9 interest;

10 (b) explains the relationship between
11 treatment options and outcomes;

12 (c) rates the quality of the evidence
13 supporting recommendations; and

14 (d) considers relevant patient
15 subgroups and preferences; and

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

18 B. In the absence of clinical guidelines that
19 meet the requirements of Subsection A of this section,
20 peer-reviewed publications may be substituted.

21 C. When a medical assistance plan restricts
22 coverage of a prescription drug for the treatment of any
23 medical condition through the use of a step therapy protocol,
24 a recipient and the practitioner prescribing the prescription
25 drug shall have access to a clear, readily accessible and

1 convenient process to request a step therapy exception
2 determination. A medical assistance plan may use its
3 existing medical exceptions process in accordance with the
4 provisions of Subsections D through I of this section to
5 satisfy this requirement. The process shall be made easily
6 accessible for recipients and practitioners on the medical
7 assistance plan's publicly accessible website.

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

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

19 (2) the prescription drug that is the
20 subject of the exception request is expected to be
21 ineffective based on the known clinical characteristics of
22 the patient and the known characteristics of the prescription
23 drug regimen;

24 (3) while under the recipient's current
25 medical assistance plan, or under the recipient's previous

1 health coverage, the recipient has tried the prescription
2 drug that is the subject of the exception request or another
3 prescription drug in the same pharmacologic class or with the
4 same mechanism of action as the prescription drug that is the
5 subject of the exception request and that prescription drug
6 was discontinued due to lack of efficacy or effectiveness,
7 diminished effect or an adverse event; or

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

12 (a) cause a significant barrier to the
13 patient's adherence to or compliance with the patient's plan
14 of care;

15 (b) worsen a comorbid condition of the
16 patient; or

17 (c) decrease the patient's ability to
18 achieve or maintain reasonable functional ability in
19 performing daily activities.

20 E. Upon the granting of an exception to a medical
21 assistance plan's step therapy protocol, a medical assistance
22 plan shall authorize continuing coverage for the prescription
23 drug that is the subject of the exception request for no less
24 than the duration of the therapeutic effect of the drug.

25 F. A medical assistance plan shall respond with

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

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

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

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

18 (1) a medical assistance plan from requiring
19 a patient to try a biosimilar, interchangeable biologic or
20 generic equivalent of a prescription drug before providing
21 coverage for the equivalent brand-name prescription drug; or

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

25 J. As used in this section, "medical necessity" or SHPAC/SB 135
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1 "medically necessary" means health care services determined
2 by a practitioner, in consultation with the medical
3 assistance plan, to be appropriate or necessary, according
4 to:

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

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

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

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

19 "59A-22-53.1. PRESCRIPTION DRUG COVERAGE--STEP THERAPY
20 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

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

1 criteria for those step therapy protocols. The clinical
2 review criteria shall be based on clinical practice
3 guidelines 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 insurers, health
12 maintenance organizations, health care plans, 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
18 tables 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
5 subgroups 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
9 meet the requirements of Subsection A of this section,
10 peer-reviewed publications may be substituted.

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

23 D. An insurer shall expeditiously grant an
24 exception to the health insurance policy's, health care
25 plan's or certificate of insurance's step therapy protocol,

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

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

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

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

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

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

8 (b) worsen a comorbid condition of the
9 patient; or

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

13 E. Upon the granting of an exception to a health
14 insurance policy's, health care plan's or certificate of
15 insurance's step therapy protocol, an insurer shall authorize
16 coverage for the prescription drug that is the subject of the
17 exception request for no less than the duration of the
18 therapeutic effect of the drug. An insurer shall include in
19 its evidence of coverage language describing an insured's
20 rights pursuant to this subsection.

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

1 respond to an exception request within the time frames
2 required pursuant to this subsection, the exception request
3 shall be granted.

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

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

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

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

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

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

25 K. Nothing in this section shall be interpreted to SHPAC/SB 135
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1 interfere with the superintendent's authority to regulate
2 prescription drug coverage benefits under other state and
3 federal law.

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

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

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

13 (3) any applicable clinical protocols or
14 practice guidelines developed by the insurer consistent with
15 federal, national and professional practice guidelines.

16 These standards shall be applied to decisions related to the
17 diagnosis or direct care and treatment of a physical or
18 behavioral health condition, illness, injury or disease."

19 SECTION 4. Section 59A-22B-8 NMSA 1978 (being Laws
20 2023, Chapter 114, Section 13) is amended to read:

21 "59A-22B-8. PRIOR AUTHORIZATION FOR PRESCRIPTION DRUGS
22 OR STEP THERAPY FOR CERTAIN CONDITIONS PROHIBITED.--

23 A. Coverage for medication approved by the federal
24 food and drug administration that is prescribed for the
25 treatment of an autoimmune disorder, cancer or a substance

1 use disorder, pursuant to a medical necessity determination,
2 shall not be subject to prior authorization, except in cases
3 in which a biosimilar, interchangeable biologic or generic
4 version is available.

5 B. A health insurer shall not impose step therapy
6 requirements before authorizing coverage for medication
7 approved by the federal food and drug administration that is
8 prescribed for the treatment of an autoimmune disorder,
9 cancer or a substance use disorder, pursuant to a medical
10 necessity determination, except in cases in which a
11 biosimilar, interchangeable biologic or generic version is
12 available."

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

15 "59A-46-52.1. PRESCRIPTION DRUG COVERAGE--STEP THERAPY
16 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

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

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

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 carriers, insurers,
7 health care plans, pharmaceutical manufacturers, pharmacy
8 benefits managers and any other entities; and 2) recuse
9 themselves if there is a conflict of interest; and

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

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

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

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

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

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

24 (d) considers relevant patient
25 subgroups and preferences; and

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

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

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

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

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

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

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

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

24 (a) cause a significant barrier to the
25 patient's adherence to or compliance with the patient's plan

1 of care;

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

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

7 E. Upon the granting of an exception to a health
8 maintenance organization contract's step therapy protocol, a
9 carrier shall authorize coverage for the prescription drug
10 that is the subject of the exception request for no less than
11 the duration of the therapeutic effect of the drug. A
12 carrier shall include in its evidence of coverage language
13 describing an enrollee's rights pursuant to this subsection.

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
17 carrier shall respond within twenty-four hours of receipt of
18 the exception request. In the event the carrier does not
19 respond to an exception request within the time frames
20 required pursuant to this subsection, the exception request
21 shall be granted.

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

25 H. After an enrollee has made an exception request SHPAC/SB 135
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1 in accordance with the provisions of this section, a carrier
2 shall authorize continued coverage of a prescription drug
3 that 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
8 contract from requiring a patient to try a biosimilar,
9 interchangeable biologic or generic equivalent of a
10 prescription drug before providing coverage for the
11 equivalent brand-name 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 superintendent shall promulgate rules as
16 may be necessary to appropriately implement the provisions of
17 this section.

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

22 L. As used in this section, "medical necessity" or
23 "medically necessary" means health care services determined
24 by a practitioner, in consultation with the carrier, to be
25 appropriate or necessary, according to:

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

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

6 (3) any applicable clinical protocols or
7 practice guidelines developed by the carrier consistent with
8 federal, national and professional practice guidelines.

9 These standards shall be applied to decisions related to the
10 diagnosis or direct care and treatment of a physical or
11 behavioral health condition, illness, injury or disease."

12 SECTION 6. Section 59A-47-47.1 NMSA 1978 (being
13 Laws 2018, Chapter 9, Section 6) is amended to read:

14 "59A-47-47.1. PRESCRIPTION DRUG COVERAGE--STEP THERAPY
15 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

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

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

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

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

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

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

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

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

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

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

24 (d) considers relevant patient
25 subgroups and preferences; and

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

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

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

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

24 (1) the prescription drug that is the
25 subject of the exception request is contraindicated or will

1 likely cause an adverse reaction by or physical or mental
2 harm to the patient;

3 (2) the prescription drug that is the
4 subject of the exception request is expected to be
5 ineffective based on the known clinical characteristics of
6 the patient and the known characteristics of the prescription
7 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
12 prescription drug in the same pharmacologic class or with the
13 same mechanism of action as the prescription drug that is the
14 subject of the exception request and that prescription drug
15 was discontinued due to lack of efficacy or effectiveness,
16 diminished effect or an adverse event; or

17 (4) the prescription drug required pursuant
18 to the step therapy protocol is not in the best interest of
19 the 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
23 of care;

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

1 (c) decrease the patient's ability to
2 achieve or maintain reasonable functional ability in
3 performing 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 coverage for the prescription drug that is the
7 subject of the exception request for no less than the
8 duration of the therapeutic effect of the drug. A health care
9 plan shall include in its evidence of coverage language
10 describing a subscriber's rights pursuant to this subsection.

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

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

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

1 request pending the determination of the exception request.

2 I. The provisions of this section shall not be
3 construed to prevent:

4 (1) a health care plan from requiring a
5 patient to try a biosimilar, interchangeable biologic or
6 generic equivalent of a prescription drug before providing
7 coverage for the equivalent brand-name prescription drug; or

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

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

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

18 L. As used in this section, "medical necessity" or
19 "medically necessary" means health care services determined
20 by a practitioner, in consultation with the health care plan,
21 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

1 societies, boards or associations; or

2 (3) any applicable clinical protocols or
3 practice guidelines developed by the health care 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 7. EXCEPTIONS.--The provisions of Sections 1
10 and 3 through 6 of this act do not apply to short-term plans
11 subject to the Short-Term Health Plan and Excepted Benefit
12 Act.

13 SECTION 8. APPLICABILITY.--The provisions of this act
14 apply to group health insurance policies, health care plans or
15 certificates of health insurance, other than small group
16 health plans, that are delivered, issued for delivery or
17 renewed in this state on or after January 1, 2025.

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