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SENATE BILL 11

53RD LEGISLATURE - STATE OF NEW MEXICO - SECOND SESSION, 2018

INTRODUCED BY

Gay G. Kernan and Elizabeth "Liz" Stefanics

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.

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 drugs for which any step therapy protocols are required shall

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1 establish clinical review criteria for those step therapy
2 protocols. The clinical review criteria shall be based on
3 clinical practice 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 group health plan
12 administrators, insurers, health maintenance organizations,
13 health care plans, pharmaceutical manufacturers, pharmacy
14 benefits managers and any other entities; and 2) recuse
15 themselves if there is a conflict of interest;

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

20 (c) offering opportunities for public
21 review and comment;

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

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

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

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

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

17 (4) the prescription drug that is the subject
18 of the exception request is not in the best interest of the
19 patient, based on medical necessity; or

20 (5) while enrolled in the enrollee's current
21 health coverage, the enrollee is stable, or while enrolled in
22 the enrollee's previous health coverage, the enrollee was
23 stable, on a prescription drug selected by the enrollee's
24 practitioner for the medical condition under consideration.

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

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1 health plan's step therapy protocol, the group health plan
2 administrator shall authorize coverage for the prescription
3 drug that is the subject of the exception request.

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

12 G. A group health plan administrator's denial of a
13 request for an exception for step therapy protocols shall be
14 subject to review and appeal pursuant to the Patient Protection
15 Act.

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

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

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

25 I. The provisions of this section shall apply only

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1 to a group health plan delivered, issued for delivery or
2 renewed on or after January 1, 2019.

3 J. As used in this section, "medically necessary"
4 means that a prescription drug is appropriate:

5 (1) to improve or preserve health, life or
6 function;

7 (2) to slow the deterioration of health, life
8 or function; or

9 (3) for the early screening, prevention,
10 evaluation, diagnosis or treatment of a disease, condition,
11 illness or injury."

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

14 "[NEW MATERIAL] MEDICAL ASSISTANCE--PRESCRIPTION DRUG
15 COVERAGE--STEP THERAPY PROTOCOLS--CLINICAL REVIEW CRITERIA--
16 EXCEPTIONS.--

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

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

25 (2) are developed and endorsed by an

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1 interdisciplinary panel of experts that manages conflicts of
2 interest among the members of the panel of experts by:

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

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

13 (c) offering opportunities for public
14 review and comment;

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

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

18 D. A medical assistance plan shall expeditiously
19 grant an exception to the medical assistance plan's step
20 therapy protocol 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;

13 (4) the prescription drug that is the subject
14 of the exception request is not in the best interest of the
15 patient, based on medical necessity; or

16 (5) while enrolled in the recipient's current
17 medical assistance plan, the recipient is stable, or while
18 enrolled in the recipient's previous health coverage, the
19 recipient was stable, on a prescription drug selected by the
20 recipient's practitioner for the medical condition under
21 consideration.

22 E. Upon the granting of an exception to a medical
23 assistance plan's step therapy protocol, a medical assistance
24 plan shall authorize coverage for the prescription drug that is
25 the subject of the exception request.

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

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

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

14 (1) a medical assistance plan from requiring a
15 patient to try a generic equivalent of a prescription drug
16 before providing coverage for the equivalent brand-name
17 prescription drug; or

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

21 I. As used in this section, "medically necessary"
22 means that a prescription drug is appropriate:

23 (1) to improve or preserve health, life or
24 function;

25 (2) to slow the deterioration of health, life

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1 or function; or

2 (3) for the early screening, prevention,
3 evaluation, diagnosis or treatment of a disease, condition,
4 illness or injury."

5 SECTION 3. A new section of Chapter 59A, Article 22 NMSA
6 1978 is enacted to read:

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

9 A. Each individual health insurance policy, health
10 care plan and certificate of health insurance delivered or
11 issued for delivery in this state that provides a prescription
12 drug benefit for which any step therapy protocols are required
13 shall establish clinical review criteria for those step therapy
14 protocols. The clinical review criteria shall be based on
15 clinical practice guidelines that:

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

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

22 (a) requiring members to: 1) disclose
23 any potential conflicts of interest with insurers, health
24 maintenance organizations, health care plans, pharmacy benefits
25 managers and any other entities; and 2) recuse themselves if

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1 there is a conflict of interest;

2 (b) using analytical and methodological
3 experts to work to provide objectivity in data analysis and
4 ranking of evidence through the preparation of evidence tables
5 and facilitating consensus; and

6 (c) offering opportunities for public
7 review and comment;

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

10 (4) are created pursuant to an explicit and
11 transparent process that:

12 (a) minimizes bias and conflicts of
13 interest;

14 (b) explains the relationship between
15 treatment options and outcomes;

16 (c) rates the quality of the evidence
17 supporting recommendations; and

18 (d) considers relevant patient subgroups
19 and preferences; and

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

22 B. In the absence of clinical guidelines that meet
23 the requirements of Subsection A of this section, peer-reviewed
24 publications may be substituted.

25 C. When a health insurance policy, health care plan

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1 or certificate of insurance restricts coverage of a
2 prescription drug for the treatment of any medical condition
3 through the use of a step therapy protocol, an insured and the
4 practitioner prescribing the prescription drug shall have
5 access to a clear, readily accessible and convenient process to
6 request a step therapy exception determination. An insurer may
7 use its existing medical exceptions process to satisfy this
8 requirement. The process shall be made easily accessible for
9 insureds and practitioners on the insurer's publicly accessible
10 website.

11 D. An insurer shall expeditiously grant an
12 exception to the health insurance policy's, health care plan's
13 or certificate of insurance's step therapy protocol if:

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

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

22 (3) while under the insured's current health
23 insurance policy, health care plan or certificate of insurance,
24 or under the insured's previous health coverage, the insured
25 has tried the prescription drug that is the subject of the

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

7 (4) the prescription drug that is the subject
8 of the exception request is not in the best interest of the
9 patient, based on medical necessity; or

10 (5) while enrolled in the insured's current
11 health insurance policy, health care plan or certificate of
12 insurance, the insured is stable, or while enrolled in the
13 insured's previous health coverage, the insured was stable, on
14 a prescription drug selected by the insured's practitioner for
15 the medical condition under consideration.

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

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

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1 exception request within the time frames required pursuant to
2 this subsection, the exception request shall be 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. The provisions of this section shall not be
7 construed to prevent:

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

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

16 I. The provisions of this section shall apply only
17 to a health insurance policy, health care plan or certificate
18 of insurance delivered, issued for delivery or renewed on or
19 after January 1, 2019.

20 J. As used in this section, "medically necessary"
21 means that a prescription drug is appropriate:

22 (1) to improve or preserve health, life or
23 function;

24 (2) to slow the deterioration of health, life
25 or function; or

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1 (3) for the early screening, prevention,
2 evaluation, diagnosis or treatment of a disease, condition,
3 illness or injury."

4 SECTION 4. A new section of Chapter 59A, Article 23 NMSA
5 1978 is enacted to read:

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

8 A. Each group or blanket health insurance policy,
9 health care plan and certificate of health insurance delivered
10 or issued for delivery in this state that provides a
11 prescription drug benefit for which any step therapy protocols
12 are required shall establish clinical review criteria for those
13 step therapy protocols. The clinical review criteria shall be
14 based on clinical practice guidelines that:

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

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

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

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1 (b) using analytical and methodological
2 experts to provide objectivity in data analysis and ranking of
3 evidence through the preparation of evidence tables and
4 facilitating consensus; and

5 (c) offering opportunities for public
6 review and comment;

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

9 (4) are created pursuant to an explicit and
10 transparent process that:

11 (a) minimizes bias and conflicts of
12 interest;

13 (b) explains the relationship between
14 treatment options and outcomes;

15 (c) rates the quality of the evidence
16 supporting recommendations; and

17 (d) considers relevant patient subgroups
18 and preferences; and

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

21 B. In the absence of clinical guidelines that meet
22 the requirements of Subsection A of this section, peer-reviewed
23 publications may be substituted.

24 C. When a health insurance policy, health care plan
25 or certificate of insurance restricts coverage of a

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1 prescription drug for the treatment of any medical condition
2 through the use of a step therapy protocol, an insured and the
3 practitioner prescribing the prescription drug shall have
4 access to a clear, readily accessible and convenient process to
5 request a step therapy exception determination. An insurer may
6 use its existing medical exceptions process to satisfy this
7 requirement. The process shall be made easily accessible for
8 insureds and practitioners on the insurer's publicly accessible
9 website.

10 D. An insurer shall expeditiously grant an
11 exception to the health insurance policy's, health care plan's
12 or certificate of insurance's step therapy protocol if:

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

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

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

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

6 (4) the prescription drug that is the subject
7 of the exception request is not in the best interest of the
8 patient, based on medical necessity; or

9 (5) while enrolled in the insured's current
10 health insurance policy, health care plan or certificate of
11 insurance, the insured is stable, or while enrolled in the
12 insured's previous health coverage, the insured was stable, on
13 a prescription drug selected by the insured's practitioner for
14 the medical condition under consideration.

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

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

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1 this subsection, the exception request shall be granted.

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

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

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

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

15 I. The provisions of this section shall apply only
16 to a health insurance policy, health care plan or certificate
17 of insurance delivered, issued for delivery or renewed on or
18 after January 1, 2019.

19 J. As used in this section, "medically necessary"
20 means that a prescription drug is appropriate:

21 (1) to improve or preserve health, life or
22 function;

23 (2) to slow the deterioration of health, life
24 or function; or

25 (3) for the early screening, prevention,

1 evaluation, diagnosis or treatment of a disease, condition,
2 illness or injury."

3 SECTION 5. A new section of the Health Maintenance
4 Organization Law is enacted to read:

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

7 A. Each individual or group health maintenance
8 organization contract delivered or issued for delivery in this
9 state that provides a prescription drug benefit for which any
10 step therapy protocols are required shall establish clinical
11 review criteria for those step therapy protocols. The clinical
12 review criteria shall be based on clinical practice guidelines
13 that:

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

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

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

25 (b) using analytical and methodological

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1 experts to work to provide objectivity in data analysis and
2 ranking of evidence through the preparation of evidence tables
3 and facilitating consensus; and

4 (c) offering opportunities for public
5 review and comment;

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

8 (4) are created pursuant to an explicit and
9 transparent process that:

10 (a) minimizes bias and conflicts of
11 interest;

12 (b) explains the relationship between
13 treatment options and outcomes;

14 (c) rates the quality of the evidence
15 supporting recommendations; and

16 (d) considers relevant patient subgroups
17 and preferences; and

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

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

23 C. When a health maintenance organization contract
24 restricts coverage of a prescription drug for the treatment of
25 any medical condition through the use of a step therapy

1 protocol, an enrollee and the practitioner prescribing the
2 prescription drug shall have access to a clear, readily
3 accessible and convenient process to request a step therapy
4 exception determination. A carrier may use its existing
5 medical exceptions process to satisfy this requirement. The
6 process shall be made easily accessible for enrollees and
7 practitioners on the carrier's publicly accessible website.

8 D. A carrier shall expeditiously grant an exception
9 to the health maintenance organization contract's step therapy
10 protocol if:

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

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

19 (3) while under the enrollee's current health
20 maintenance organization contract, or under the enrollee's
21 previous health coverage, the enrollee has tried the
22 prescription drug that is the subject of the exception request
23 or another prescription drug in the same pharmacologic class or
24 with the same mechanism of action as the prescription drug that
25 is the subject of the exception request and that prescription

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1 drug was discontinued due to lack of efficacy or effectiveness,
2 diminished effect or an adverse event;

3 (4) the prescription drug that is the subject
4 of the exception request is not in the best interest of the
5 patient, based on medical necessity; or

6 (5) while enrolled in the enrollee's current
7 health maintenance organization contract, the enrollee is
8 stable, or while enrolled in the enrollee's previous health
9 coverage, the enrollee was stable, on a prescription drug
10 selected by the enrollee's practitioner for the medical
11 condition under consideration.

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

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

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

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1 H. The provisions of this section shall not be
2 construed to prevent:
3 (1) a health maintenance organization contract
4 from requiring a patient to try a generic equivalent of a
5 prescription drug before providing coverage for the equivalent
6 brand-name prescription drug; or
7 (2) a practitioner from prescribing a
8 prescription drug that the practitioner has determined to be
9 medically necessary.

10 I. The provisions of this section shall apply only
11 to a health maintenance organization contract delivered, issued
12 for delivery or renewed on or after January 1, 2019.

13 J. As used in this section, "medically necessary"
14 means that a prescription drug is appropriate:
15 (1) to improve or preserve health, life or
16 function;
17 (2) to slow the deterioration of health, life
18 or function; or
19 (3) for the early screening, prevention,
20 evaluation, diagnosis or treatment of a disease, condition,
21 illness or injury."

22 **SECTION 6.** A new section of the Nonprofit Health Care
23 Plan Law is enacted to read:

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

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1 A. Each individual or group nonprofit health care
2 plan contract delivered or issued for delivery in this state
3 that provides a prescription drug benefit for which any step
4 therapy protocols are required shall establish clinical review
5 criteria for those step therapy protocols. The clinical review
6 criteria shall be based on 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 health care plans,
15 insurers, health maintenance organizations, pharmaceutical
16 manufacturers, pharmacy benefits managers and any other
17 entities; and 2) recuse themselves if there is a conflict of
18 interest;

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

23 (c) offering opportunities for public
24 review and comment;

25 (3) are based on high-quality studies,

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1 research and medical practice;

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

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

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

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

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

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

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

17 C. When a health care plan restricts coverage of a
18 prescription drug for the treatment of any medical condition
19 through the use of a step therapy protocol, a subscriber and
20 the 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. A health care
23 plan may use its existing medical exceptions process to satisfy
24 this requirement. The process shall be made easily accessible
25 for subscribers and practitioners on the health care plan's

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1 publicly accessible website.

2 D. A health care plan shall expeditiously grant an
3 exception to the health care plan's step therapy protocol 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;

21 (4) the prescription drug that is the subject
22 of the exception request is not in the best interest of the
23 patient, based on medical necessity; or

24 (5) while enrolled in the subscriber's current
25 health care plan, the subscriber is stable, or while enrolled

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1 in the subscriber's previous health coverage, the subscriber
2 was stable, on a prescription drug selected by the subscriber's
3 practitioner for the medical condition under consideration.

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.

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

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

19 H. The provisions of this section shall not be
20 construed to prevent:

21 (1) a health care plan from requiring a
22 patient to try a generic equivalent of a prescription drug
23 before providing coverage for the equivalent brand-name
24 prescription drug; or

25 (2) a practitioner from prescribing a

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1 prescription drug that the practitioner has determined to be
2 medically necessary.

3 I. The provisions of this section shall apply only
4 to a health care plan delivered, issued for delivery or renewed
5 on or after January 1, 2019.

6 J. As used in this section, "medically necessary"
7 means that a prescription drug is appropriate:

8 (1) to improve or preserve health, life or
9 function;

10 (2) to slow the deterioration of health, life
11 or function; or

12 (3) for the early screening, prevention,
13 evaluation, diagnosis or treatment of a disease, condition,
14 illness or injury."

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