

1 HOUSE BILL 244

2 **53RD LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2017**

3 INTRODUCED BY

4 Elizabeth "Liz" Thomson

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10 AN ACT

11 RELATING TO HEALTH COVERAGE; ENACTING NEW SECTIONS OF THE
12 HEALTH CARE PURCHASING ACT, THE PUBLIC ASSISTANCE ACT, THE NEW
13 MEXICO INSURANCE CODE, THE HEALTH MAINTENANCE ORGANIZATION LAW
14 AND THE NONPROFIT HEALTH CARE PLAN LAW TO ESTABLISH GUIDELINES
15 RELATING TO STEP THERAPY FOR PRESCRIPTION DRUG COVERAGE.

16
17 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

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

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

22 A. Group health coverage, including any form of
23 self-insurance, offered, issued or renewed under the Health
24 Care Purchasing Act that provides coverage for prescription
25 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:

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- 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. A group health administrator shall continually
15 update clinical review criteria for step therapy protocols
16 pursuant to a review of new evidence, research and newly
17 developed treatments.

18 D. The provisions of this section shall not be
19 construed to require a group health plan administrator or the
20 state to establish a new entity to develop clinical review
21 criteria used for step therapy protocols.

22 E. When a group health plan restricts coverage of a
23 prescription drug for the treatment of any medical condition
24 through the use of a step therapy protocol, an enrollee and the
25 practitioner prescribing the prescription drug shall have

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1 access to a clear, readily accessible and convenient process to
2 request a step therapy exception determination. A group health
3 plan may use its existing medical exceptions process to satisfy
4 this requirement. The process shall be made easily accessible
5 for enrollees and practitioners on the group health plan's
6 publicly accessible website.

7 F. A group health plan shall expeditiously grant an
8 exception to the group health plan's step therapy protocol if:

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

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

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

25 (4) the prescription drug that is the subject

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1 of the exception request is not in the best interest of the
2 patient, based on medical necessity; or

3 (5) while enrolled in the enrollee's current
4 health coverage, the enrollee is stable, or while enrolled in
5 the enrollee's previous health coverage, the enrollee was
6 stable, on a prescription drug selected by the enrollee's
7 practitioner for the medical condition under consideration.

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

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

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

24 J. The provisions of this section shall not be
25 construed to prevent a:

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

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

8 K. The provisions of this section shall apply only
9 to a group health plan delivered, issued for delivery or
10 renewed on or after January 1, 2018.

11 L. As used in this section, "medically necessary"
12 means that a prescription drug is appropriate:

13 (1) to improve or preserve health, life or
14 function;

15 (2) to slow the deterioration of health, life
16 or function; or

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

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

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

25 A. By January 1, 2018, the secretary shall require

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1 any medical assistance plan for which any step therapy
2 protocols are required to establish clinical review criteria
3 for those step therapy protocols. The clinical review criteria
4 shall be based on 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 health care plans,
13 medical assistance plans, health maintenance organizations,
14 pharmaceutical manufacturers, pharmacy benefits managers and
15 any other entities; and 2) recuse themselves if there is a
16 conflict of interest;

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; and

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

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

25 (4) are created pursuant to an explicit and

1 transparent process that:

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

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

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

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

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

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

15 C. A medical assistance plan shall continually
16 update clinical review criteria for step therapy protocols
17 pursuant to a review of new evidence, research and newly
18 developed treatments.

19 D. The provisions of this section shall not be
20 construed to require a medical assistance plan to establish a
21 new entity to develop clinical review criteria used for step
22 therapy protocols.

23 E. When a medical assistance plan restricts
24 coverage of a prescription drug for the treatment of any
25 medical condition through the use of a step therapy protocol, a

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

9 F. A medical assistance plan shall expeditiously
10 grant an exception to the medical assistance plan's step
11 therapy protocol 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 recipient's current
21 medical assistance plan, or under the recipient's previous
22 health coverage, the recipient has tried the prescription drug
23 that is the subject of the exception request or another
24 prescription drug in the same pharmacologic class or with the
25 same mechanism of action as the prescription drug that is the

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

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

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

13 G. Upon the granting of an exception to a medical
14 assistance plan's step therapy protocol, a medical assistance
15 plan shall authorize coverage for the prescription drug that is
16 the subject of the exception request.

17 H. A medical assistance plan shall respond to a
18 recipient's exception request within seventy-two hours of
19 receipt. In cases where exigent circumstances exist, a medical
20 assistance plan shall respond within twenty-four hours of
21 receipt of the exception request. In the event the medical
22 assistance plan does not respond to an exception request within
23 the time frames required pursuant to this subsection, the
24 exception request shall be granted.

25 I. A medical assistance plan's denial of a request

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1 for an exception for step therapy protocols shall be subject to
2 review and appeal pursuant to department rules.

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

5 (1) a medical assistance plan from requiring a
6 patient to try a generic equivalent of a prescription drug
7 before providing coverage for the equivalent brand-name
8 prescription drug; or

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

12 K. As used in this section, "medically necessary"
13 means that a prescription drug is appropriate:

14 (1) to improve or preserve health, life or
15 function;

16 (2) to slow the deterioration of health, life
17 or function; or

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

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

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

25 A. Each individual health insurance policy, health

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

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

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

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

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

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

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. An insurer shall continually update clinical
17 review criteria for step therapy protocols pursuant to a review
18 of new evidence, research and newly developed treatments.

19 D. The provisions of this section shall not be
20 construed to require an insurer to establish a new entity to
21 develop clinical review criteria used for step therapy
22 protocols.

23 E. When a health insurance policy, health care plan
24 or certificate of insurance restricts coverage of a
25 prescription drug for the treatment of any medical condition

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

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

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;

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

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

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

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

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

4 J. The provisions of this section shall not be
5 construed to prevent:

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

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

14 K. The provisions of this section shall apply only
15 to a health insurance policy, health care plan or certificate
16 of insurance delivered, issued for delivery or renewed on or
17 after January 1, 2018.

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

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

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

24 (3) for the early screening, prevention,
25 evaluation, diagnosis or treatment of a disease, condition,

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1 illness or injury."

2 SECTION 4. A new section of Chapter 59A, Article 23 NMSA
3 1978 is enacted to read:

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

6 A. Each group or blanket health insurance policy,
7 health care plan and certificate of health insurance delivered
8 or issued for delivery in this state that provides a
9 prescription drug benefit for which any step therapy protocols
10 are required shall establish clinical review criteria for those
11 step therapy protocols. The clinical review criteria shall be
12 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 insurers, health
21 maintenance organizations, health care plans, pharmacy benefits
22 managers and any other entities; and 2) recuse themselves if
23 there is a conflict of interest;

24 (b) using analytical and methodological
25 experts to provide objectivity in data analysis and ranking of

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1 evidence through the preparation of evidence tables and
2 facilitating consensus; and

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

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

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

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

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

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

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

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

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

22 C. An insurer shall continually update clinical
23 review criteria for step therapy protocols pursuant to a review
24 of new evidence, research and newly developed treatments.

25 D. The provisions of this section shall not be

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1 construed to require an insurer to establish a new entity to
2 develop clinical review criteria used for step therapy
3 protocols.

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

15 F. An insurer shall expeditiously grant an
16 exception to the health insurance policy's, health care plan's
17 or certificate of insurance's step therapy protocol if:

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

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

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

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

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

20 G. Upon the granting of an exception to a health
21 insurance policy, health care plan or certificate of
22 insurance's step therapy protocol, an insurer shall authorize
23 coverage for the prescription drug that is the subject of the
24 exception request.

25 H. An insurer shall respond to an insured's

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

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

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

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

20 K. The provisions of this section shall apply only
21 to a health insurance policy, health care plan or certificate
22 of insurance delivered, issued for delivery or renewed on or
23 after January 1, 2018.

24 L. As used in this section, "medically necessary"
25 means that a prescription drug is appropriate:

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

3 (2) to slow the deterioration of health, life
4 or function; or

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

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

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

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

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

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

25 (a) requiring members to: 1) disclose

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

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

9 (c) offering opportunities for public
10 review and comment;

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

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

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

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

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

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

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

25 B. In the absence of clinical guidelines that meet

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1 the requirements of Subsection A of this section, peer-reviewed
2 publications may be substituted.

3 C. A carrier shall continually update clinical
4 review criteria for step therapy protocols pursuant to a review
5 of new evidence, research and newly developed treatments.

6 D. The provisions of this section shall not be
7 construed to require a carrier to establish a new entity to
8 develop clinical review criteria used for step therapy
9 protocols.

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

20 F. A carrier shall expeditiously grant an exception
21 to the health maintenance organization contract's step therapy
22 protocol 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 enrollee's current health
7 maintenance organization contract, or under the enrollee's
8 previous health coverage, the enrollee has tried the
9 prescription drug that is the subject of the exception request
10 or another prescription drug in the same pharmacologic class or
11 with the same mechanism of action as the prescription drug that
12 is the subject of the exception request and that prescription
13 drug was discontinued due to lack of efficacy or effectiveness,
14 diminished effect or an adverse event;

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

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

24 G. Upon the granting of an exception to a health
25 maintenance organization contract's step therapy protocol, a

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1 carrier shall authorize coverage for the prescription drug that
2 is the subject of the exception request.

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

10 I. A carrier's denial of a request for an exception
11 for step therapy protocols shall be subject to review and
12 appeal pursuant to the Patient Protection Act.

13 J. The provisions of this section shall not be
14 construed to prevent:

15 (1) a health maintenance organization contract
16 from requiring a patient to try a generic equivalent of a
17 prescription drug before providing coverage for the equivalent
18 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 K. The provisions of this section shall apply only
23 to a health maintenance organization contract delivered, issued
24 for delivery or renewed on or after January 1, 2018.

25 L. As used in this section, "medically necessary"

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1 means that a prescription drug is appropriate:

2 (1) to improve or preserve health, life or
3 function;

4 (2) to slow the deterioration of health, life
5 or function; or

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

9 SECTION 6. A new section of the Nonprofit Health Care
10 Plan Law is enacted to read:

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

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

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

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

25 (a) requiring members to: 1) disclose

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

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

10 (c) offering opportunities for public
11 review and comment;

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. A health care plan shall continually update
5 clinical review criteria for step therapy protocols pursuant to
6 a review of new evidence, research and newly developed
7 treatments.

8 D. The provisions of this section shall not be
9 construed to require a health care plan to establish a new
10 entity to develop clinical review criteria used for step
11 therapy protocols.

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

22 F. A health care plan shall expeditiously grant an
23 exception to the health care plan's step therapy protocol if:

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

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

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

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

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

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

24 G. Upon the granting of an exception to a health
25 care plan's step therapy protocol, a health care plan shall

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1 authorize coverage for the prescription drug that is the
2 subject of the exception request.

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

11 I. A health care plan's denial of a request for an
12 exception for step therapy protocols shall be subject to review
13 and appeal pursuant to the Patient Protection Act.

14 J. The provisions of this section shall not be
15 construed to prevent:

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

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

23 K. The provisions of this section shall apply only
24 to a health care plan delivered, issued for delivery or renewed
25 on or after January 1, 2018.

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