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HOUSE BILL 42

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

INTRODUCED BY

Elizabeth "Liz" Thomson and Monica Youngblood

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:

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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. 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

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

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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."