

1 SENATE BILL 179

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

3 INTRODUCED BY

4 Elizabeth "Liz" Stefanics

5  
6  
7  
8  
9  
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

.205739.1

underscoring material = new  
~~[bracketed material] = delete~~

underscoring material = new  
~~[bracketed material] = delete~~

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:

.205739.1

underscoring material = new  
~~[bracketed material] = delete~~

- 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

.205739.1

underscoring material = new  
~~[bracketed material] = delete~~

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

.205739.1

underscoring material = new  
~~[bracketed material] = delete~~

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:

.205739.1

underscored material = new  
[bracketed material] = delete

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

.205739.1

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



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

underscored material = new  
[bracketed material] = delete

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

.205739.1

underscoring material = new  
~~[bracketed material]~~ = delete

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;

.205739.1

underscoring material = new  
~~[bracketed material] = delete~~

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

.205739.1

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.

underscored material = new  
[bracketed material] = delete

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,

.205739.1



underscoring material = new  
[bracketed material] = delete

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

.205739.1

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

underscoring material = new  
~~[bracketed material] = delete~~

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;

.205739.1

underscoring material = new  
~~[bracketed material] = delete~~

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

.205739.1

underscored material = new  
~~[bracketed material] = delete~~

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:

.205739.1

underscored material = new  
[bracketed material] = delete

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

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

underscoring material = new  
~~[bracketed material] = delete~~

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



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

underscored material = new  
~~[bracketed material] = delete~~

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"

.205739.1

underscored material = new  
[bracketed material] = delete

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

.205739.1

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.

underscoring material = new  
~~[bracketed material] = delete~~

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

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

underscoring material = new  
~~[bracketed material] = delete~~

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.

.205739.1

underscoring material = new  
~~[bracketed material] = delete~~

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

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

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

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

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