

SENATE CORPORATIONS AND TRANSPORTATION COMMITTEE SUBSTITUTE FOR  
SENATE PUBLIC AFFAIRS COMMITTEE SUBSTITUTE FOR  
SENATE BILL 11

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

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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underscored 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; and

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;

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

22 (4) are created pursuant to an explicit and  
23 transparent process that:

24 (a) minimizes bias and conflicts of  
25 interest;

1 (b) explains the relationship between  
2 treatment options and outcomes;

3 (c) rates the quality of the evidence  
4 supporting recommendations; and

5 (d) considers relevant patient subgroups  
6 and preferences; and

7 (5) take into account the needs of atypical  
8 patient populations and diagnoses.

9 B. In the absence of clinical guidelines that meet  
10 the requirements of Subsection A of this section, peer-reviewed  
11 publications may be substituted.

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

23 D. A group health plan shall expeditiously grant an  
24 exception to the group health plan's step therapy protocol,  
25 based on medical necessity and a clinically valid explanation

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1 from the patient's prescribing practitioner as to why a drug on  
2 the plan's formulary that is therapeutically equivalent to the  
3 prescribed drug should not be substituted for the prescribed  
4 drug, if:

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

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

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

21 (4) the prescription drug that is the subject  
22 of the exception request is not in the best interest of the  
23 patient.

24 E. Upon the granting of an exception to a group  
25 health plan's step therapy protocol, the group health plan

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

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

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

15 H. After an enrollee has made an exception request  
16 in accordance with the provisions of this section, a group  
17 health plan shall authorize continued coverage of a  
18 prescription drug that is the subject of the exception request  
19 pending the determination of the exception request.

20 I. The provisions of this section shall not be  
21 construed to prevent a:

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

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1 (2) practitioner from prescribing a  
2 prescription drug that the practitioner has determined to be  
3 medically necessary.

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

7 K. As used in this section, "medical necessity" or  
8 "medically necessary" means health care services determined by  
9 a practitioner, in consultation with the group health plan  
10 administrator, to be appropriate or necessary according to:

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

13 (2) practice guidelines developed by the  
14 federal government or national or professional medical  
15 societies, boards or associations; or

16 (3) any applicable clinical protocols or  
17 practice guidelines developed by the group health plan  
18 consistent with federal, national and professional practice  
19 guidelines. These standards shall be applied to decisions  
20 related to the diagnosis or direct care and treatment of a  
21 physical or behavioral health condition, illness, injury or  
22 disease."

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

25 "[NEW MATERIAL] MEDICAL ASSISTANCE--PRESCRIPTION DRUG

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1 COVERAGE--STEP THERAPY PROTOCOLS--CLINICAL REVIEW CRITERIA--  
2 EXCEPTIONS.--

3 A. By January 1, 2019, the secretary shall require  
4 any medical assistance plan for which any step therapy  
5 protocols are required to establish clinical review criteria  
6 for those step therapy protocols. The clinical review criteria  
7 shall be based on clinical practice guidelines that:

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

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

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

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

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. When a medical assistance plan restricts  
17 coverage of a prescription drug for the treatment of any  
18 medical condition through the use of a step therapy protocol, a  
19 recipient and the practitioner prescribing the prescription  
20 drug shall have access to a clear, readily accessible and  
21 convenient process to request a step therapy exception  
22 determination. A medical assistance plan may use its existing  
23 medical exceptions process in accordance with the provisions of  
24 Subsections D through I of this section to satisfy this  
25 requirement. The process shall be made easily accessible for

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1 recipients and practitioners on the medical assistance plan's  
2 publicly accessible website.

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

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

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

18 (3) while under the recipient's current  
19 medical assistance plan, or under the recipient's previous  
20 health coverage, the recipient has tried the prescription drug  
21 that is the subject of the exception request or another  
22 prescription drug in the same pharmacologic class or with the  
23 same mechanism of action as the prescription drug that is the  
24 subject of the exception request and that prescription drug was  
25 discontinued due to lack of efficacy or effectiveness,

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1 diminished effect or an adverse event; or

2 (4) the prescription drug that is the subject  
3 of the exception request is not in the best interest of the  
4 patient, based on medical necessity and an explanation from the  
5 patient's prescribing practitioner as to why a drug on the  
6 medical assistance plan's formulary that is therapeutically  
7 equivalent to the prescribed drug should not be substituted for  
8 the prescribed drug.

9 E. Upon the granting of an exception to a medical  
10 assistance plan's step therapy protocol, a medical assistance  
11 plan shall authorize coverage for the prescription drug that is  
12 the subject of the exception request.

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

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

24 H. After a recipient has made an exception request  
25 in accordance with the provisions of this section, a medical

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1 assistance plan shall authorize continued coverage of a  
2 prescription drug that is the subject of the exception request  
3 pending the determination of the exception request.

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

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

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

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

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

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

22 (3) any applicable clinical protocols or  
23 practice guidelines developed by the medical assistance plan  
24 consistent with federal, national and professional practice  
25 guidelines. These standards shall be applied to decisions

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1 related to the diagnosis or direct care and treatment of a  
2 physical or behavioral health condition, illness, injury or  
3 disease."

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

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

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

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

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. When a health insurance policy, health care plan  
23 or certificate of insurance restricts coverage of a  
24 prescription drug for the treatment of any medical condition  
25 through the use of a step therapy protocol, an insured and the

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

9 D. 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, based on  
12 medical necessity and a clinically valid explanation from the  
13 patient's prescribing practitioner as to why a drug on the  
14 health insurance policy's, health care plan's or certificate of  
15 insurance's formulary that is therapeutically equivalent to the  
16 prescribed drug should not be substituted for the prescribed  
17 drug, 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; or

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 and an explanation from the  
14 patient's prescribing practitioner as to why a drug on the  
15 health insurance plan, health care plan or certificate of  
16 insurance formulary that is therapeutically equivalent to the  
17 prescribed drug should not be substituted for the prescribed  
18 drug.

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

24 F. An insurer shall respond with its decision on an  
25 insured's exception request within seventy-two hours of

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

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

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

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

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

25 J. The provisions of this section shall apply only

1 to a health insurance policy, health care plan or certificate  
2 of insurance delivered, issued for delivery or renewed on or  
3 after January 1, 2019.

4 K. The superintendent shall promulgate rules as may  
5 be necessary to appropriately implement the provisions of this  
6 section.

7 L. Nothing in this section shall be interpreted to  
8 interfere with the superintendent's authority to regulate  
9 prescription drug coverage benefits under other state and  
10 federal law.

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

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

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

20 (3) any applicable clinical protocols or  
21 practice guidelines developed by the insurer consistent with  
22 federal, national and professional practice guidelines. These  
23 standards shall be applied to decisions related to the  
24 diagnosis or direct care and treatment of a physical or  
25 behavioral health condition, illness, injury or disease."

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

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

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

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

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

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

23                           (b) using analytical and methodological  
24 experts to provide objectivity in data analysis and ranking of  
25 evidence through the preparation of evidence tables and

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1 facilitating consensus;

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

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

6 (a) minimizes bias and conflicts of  
7 interest;

8 (b) explains the relationship between  
9 treatment options and outcomes;

10 (c) rates the quality of the evidence  
11 supporting recommendations; and

12 (d) considers relevant patient subgroups  
13 and preferences; and

14 (5) take into account the needs of atypical  
15 patient populations and diagnoses.

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

19 C. When a health insurance policy, health care plan  
20 or certificate of insurance restricts coverage of a  
21 prescription drug for the treatment of any medical condition  
22 through the use of a step therapy protocol, an insured and the  
23 practitioner prescribing the prescription drug shall have  
24 access to a clear, readily accessible and convenient process to  
25 request a step therapy exception determination. An insurer may

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1 use its existing medical exceptions process in accordance with  
2 the provisions of Subsections D through I of this section to  
3 satisfy this requirement. The process shall be made easily  
4 accessible for insureds and practitioners on the insurer's  
5 publicly accessible website.

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

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

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

23 (3) while under the insured's current health  
24 insurance policy, health care plan or certificate of insurance,  
25 or under the insured's previous health coverage, the insured

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

8 (4) the prescription drug that is the subject  
9 of the exception request is not in the best interest of the  
10 patient, based on medical necessity and an explanation from the  
11 patient's prescribing practitioner as to why a drug on the  
12 health insurance plan, health care plan or certificate of  
13 insurance formulary that is therapeutically equivalent to the  
14 prescribed drug should not be substituted for the prescribed  
15 drug.

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

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

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

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

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

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

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

22 J. The provisions of this section shall apply only  
23 to a health insurance policy, health care plan or certificate  
24 of insurance delivered, issued for delivery or renewed on or  
25 after January 1, 2019.

1           K. The superintendent shall promulgate rules as may  
2 be necessary to appropriately implement the provisions of this  
3 section.

4           L. Nothing in this section shall be interpreted to  
5 interfere with the superintendent's authority to regulate  
6 prescription drug coverage benefits under other state and  
7 federal law.

8           M. As used in this section, "medical necessity" or  
9 "medically necessary" means health care services determined by  
10 a practitioner, in consultation with the insurer, to be  
11 appropriate or necessary, according to:

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

14                   (2) practice guidelines developed by the  
15 federal government or national or professional medical  
16 societies, boards or associations; or

17                   (3) any applicable clinical protocols or  
18 practice guidelines developed by the insurer consistent with  
19 federal, national and professional practice guidelines. These  
20 standards shall be applied to decisions related to the  
21 diagnosis or direct care and treatment of a physical or  
22 behavioral health condition, illness, injury or disease."

23           **SECTION 5.** A new section of the Health Maintenance  
24 Organization Law is enacted to read:

25           "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY

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1 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

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

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

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

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

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

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. When a health maintenance organization contract  
17 restricts coverage of a prescription drug for the treatment of  
18 any medical condition through the use of a step therapy  
19 protocol, an enrollee and the practitioner prescribing the  
20 prescription drug shall have access to a clear, readily  
21 accessible and convenient process to request a step therapy  
22 exception determination. A carrier may use its existing  
23 medical exceptions process in accordance with the provisions of  
24 Subsections D through I of this section to satisfy this  
25 requirement. The process shall be made easily accessible for

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1 enrollees and practitioners on the carrier's publicly  
2 accessible website.

3 D. A carrier shall expeditiously grant an exception  
4 to the health maintenance organization contract's step therapy  
5 protocol, based on medical necessity and a clinically valid  
6 explanation from the patient's prescribing practitioner as to  
7 why a drug on the health maintenance organization contract's  
8 formulary that is therapeutically equivalent to the prescribed  
9 drug should not be substituted for the prescribed drug, if:

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

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

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

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1 diminished effect or an adverse event; or

2 (4) the prescription drug that is the subject  
3 of the exception request is not in the best interest of the  
4 patient, based on medical necessity and an explanation from the  
5 patient's prescribing practitioner as to why a drug on the  
6 health maintenance organization contract formulary that is  
7 therapeutically equivalent to the prescribed drug should not be  
8 substituted for the prescribed drug.

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

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

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

24 H. After an enrollee has made an exception request  
25 in accordance with the provisions of this section, a carrier

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1 shall authorize continued coverage of a prescription drug that  
2 is the subject of the exception request pending the  
3 determination of the exception request.

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

6 (1) a health maintenance organization contract  
7 from requiring a patient to try a generic equivalent of a  
8 prescription drug before providing coverage for the equivalent  
9 brand-name prescription drug; or

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

13 J. The provisions of this section shall apply only  
14 to a health maintenance organization contract delivered, issued  
15 for delivery or renewed on or after January 1, 2019.

16 K. The superintendent shall promulgate rules as may  
17 be necessary to appropriately implement the provisions of this  
18 section.

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

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

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1 appropriate or necessary, according to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 and an explanation from the  
19 patient's prescribing practitioner as to why a drug on the  
20 health care plan formulary that is therapeutically equivalent  
21 to the prescribed drug should not be substituted for the  
22 prescribed drug.

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

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1 subject of the exception request.

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

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

13 H. After a subscriber has made an exception request  
14 in accordance with the provisions of this section, a health  
15 care plan shall authorize continued coverage of a prescription  
16 drug that is the subject of the exception request pending the  
17 determination of the exception request.

18 I. The provisions of this section shall not be  
19 construed to prevent:

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

24 (2) a practitioner from prescribing a  
25 prescription drug that the practitioner has determined to be

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1 medically necessary.

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

5 K. The superintendent shall promulgate rules as may  
6 be necessary to appropriately implement the provisions of this  
7 section.

8 L. Nothing in this section shall be interpreted to  
9 interfere with the superintendent's authority to regulate  
10 prescription drug coverage benefits under other state and  
11 federal law.

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

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

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

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

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

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