

1 SENATE BILL 135

2 **56TH LEGISLATURE - STATE OF NEW MEXICO - SECOND SESSION, 2024**

3 INTRODUCED BY

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5 Siah Correa Hemphill and Antonio Maestas and  
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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 AND  
16 ELIMINATE STEP THERAPY REQUIREMENTS FOR CERTAIN CONDITIONS.

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

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

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

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

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

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;

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

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

25 (a) minimizes bias and conflicts of

1 interest;

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

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

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

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

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

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

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

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

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

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

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

22 (4) the prescription drug required pursuant to  
23 the step therapy protocol is not in the best interest of the  
24 patient, based on clinical appropriateness, because the  
25 patient's use of the prescription drug is expected to:

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1 (a) cause a significant barrier to the  
2 patient's adherence to or compliance with the patient's plan of  
3 care;

4 (b) worsen a comorbid condition of the  
5 patient; or

6 (c) decrease the patient's ability to  
7 achieve or maintain reasonable functional ability in performing  
8 daily activities.

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

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

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

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1           H. After an enrollee has made an exception request  
2 in accordance with the provisions of this section, a group  
3 health plan shall authorize continued coverage of a  
4 prescription drug that is the subject of the exception request  
5 pending the determination of the exception request.

6           I. The provisions of this section shall not be  
7 construed to prevent a:

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

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

15           J. The provisions of this section shall apply only  
16 to a group health plan delivered, issued for delivery or  
17 renewed on or after January 1, 2025.

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

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

24                   (2) practice guidelines developed by the  
25 federal government or national or professional medical

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1 societies, boards or associations; or

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

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

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

14 A. By January 1, 2025, the secretary shall require  
15 any medical assistance plan for which any step therapy  
16 protocols are required to establish clinical review criteria  
17 for those step therapy protocols. The clinical review criteria  
18 shall be based on clinical practice guidelines that:

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

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

25 (a) requiring members to: 1) disclose

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

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;

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

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

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

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

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

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

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

24 B. In the absence of clinical guidelines that meet  
25 the requirements of Subsection A of this section, peer-reviewed



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1 publications may be substituted.

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

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

13 (4) the prescription drug required pursuant to  
14 the step therapy protocol is not in the best interest of the  
15 patient, based on clinical appropriateness, because the  
16 patient's use of the prescription drug is expected to:

17 (a) cause a significant barrier to the  
18 patient's adherence to or compliance with the patient's plan of  
19 care;

20 (b) worsen a comorbid condition of the  
21 patient; or

22 (c) decrease the patient's ability to  
23 achieve or maintain reasonable functional ability in performing  
24 daily activities.

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

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1 assistance plan's step therapy protocol, a medical assistance  
2 plan shall authorize continuing coverage for the life of the  
3 patient for the prescription drug that is the subject of the  
4 exception request.

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

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

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

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

23 (1) a medical assistance plan from requiring a  
24 patient to try a generic equivalent of a prescription drug  
25 before providing coverage for the equivalent brand-name

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1 prescription drug; or

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

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

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

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

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

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

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

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

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

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

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

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;

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 health insurance policy, health care plan  
15 or certificate of insurance restricts coverage of a  
16 prescription drug for the treatment of any medical condition  
17 through the use of a step therapy protocol, an insured and the  
18 practitioner prescribing the prescription drug shall have  
19 access to a clear, readily accessible and convenient process to  
20 request a step therapy exception determination. An insurer may  
21 use its existing medical exceptions process in accordance with  
22 the provisions of Subsections D through I of this section to  
23 satisfy this requirement. The process shall be made easily  
24 accessible for insureds and practitioners on the insurer's  
25 publicly accessible website.

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1           D. An insurer shall expeditiously grant an  
2 exception to the health insurance policy's, health care plan's  
3 or certificate of insurance's step therapy protocol, based on  
4 medical necessity and a clinically valid explanation from the  
5 patient's prescribing practitioner as to why a drug on the  
6 health insurance policy's, health care plan's or certificate of  
7 insurance's formulary that is therapeutically equivalent to the  
8 prescribed drug should not be substituted for the prescribed  
9 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 insured's current health  
19 insurance policy, health care plan or certificate of insurance,  
20 or under the insured's previous health coverage, the insured  
21 has tried the prescription drug that is the subject of the  
22 exception request or another prescription drug in the same  
23 pharmacologic class or with the same mechanism of action as the  
24 prescription drug that is the subject of the exception request  
25 and that prescription drug was discontinued due to lack of

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1 efficacy or effectiveness, diminished effect or an adverse  
2 event; or

3 (4) the prescription drug required pursuant to  
4 the step therapy protocol is not in the best interest of the  
5 patient, based on clinical appropriateness, because the  
6 patient's use of the prescription drug is expected to:

7 (a) cause a significant barrier to the  
8 patient's adherence to or compliance with the patient's plan of  
9 care;

10 (b) worsen a comorbid condition of the  
11 patient; or

12 (c) decrease the patient's ability to  
13 achieve or maintain reasonable functional ability in performing  
14 daily activities.

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

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

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

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

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

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

21 J. The provisions of this section shall apply only  
22 to a health insurance policy, health care plan or certificate  
23 of insurance delivered, issued for delivery or renewed on or  
24 after January 1, 2025.

25 K. The superintendent shall promulgate rules as may

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1 be necessary to appropriately implement the provisions of this  
2 section.

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

7 M. As used in this section, "medical necessity" or  
8 "medically necessary" means health care services determined by  
9 a practitioner, in consultation with the insurer, to be  
10 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 insurer consistent with  
18 federal, national and professional practice guidelines. These  
19 standards shall be applied to decisions related to the  
20 diagnosis or direct care and treatment of a physical or  
21 behavioral health condition, illness, injury or disease."

22 SECTION 4. Section 59A-22B-8 NMSA 1978 (being Laws 2023,  
23 Chapter 114, Section 13) is amended to read:

24 "59A-22B-8. PRIOR AUTHORIZATION FOR PRESCRIPTION DRUGS OR  
25 STEP THERAPY FOR ~~[SUBSTANCE USE DISORDER]~~ CERTAIN CONDITIONS

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1 PROHIBITED.--

2 A. Coverage for medication approved by the federal  
3 food and drug administration that is prescribed for the  
4 treatment of an autoimmune disorder, a behavioral health  
5 condition, cancer or a substance use disorder, pursuant to a  
6 health care provider's medical necessity determination, shall  
7 not be subject to prior authorization, except in cases in which  
8 a generic version is available.

9 B. A health insurer shall not impose step therapy  
10 requirements before authorizing coverage for medication  
11 approved by the federal food and drug administration that is  
12 prescribed for the treatment of an autoimmune disorder, a  
13 behavioral health condition, cancer or a substance use  
14 disorder, pursuant to a health care provider's medical  
15 necessity determination, except in cases in which a generic  
16 version is available."

17 SECTION 5. A new section of Chapter 59A, Article 23 NMSA  
18 1978 is enacted to read:

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

21 A. Each group or blanket health insurance policy,  
22 health care plan and certificate of health insurance delivered  
23 or issued for delivery in this state that provides a  
24 prescription drug benefit for which any step therapy protocols  
25 are required shall establish clinical review criteria for those

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1 step therapy protocols. The clinical review criteria shall be  
2 based on clinical practice guidelines that:

3 (1) recommend that the prescription drugs  
4 subject to step therapy protocols be taken in the specific  
5 sequence required by the step therapy protocol;

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

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

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

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

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

22 (a) minimizes bias and conflicts of  
23 interest;

24 (b) explains the relationship between  
25 treatment options and outcomes;

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1 (c) rates the quality of the evidence  
2 supporting recommendations; and

3 (d) considers relevant patient subgroups  
4 and preferences; and

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

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

10 C. When a health insurance policy, health care plan  
11 or certificate of insurance restricts coverage of a  
12 prescription drug for the treatment of any medical condition  
13 through the use of a step therapy protocol, an insured and the  
14 practitioner prescribing the prescription drug shall have  
15 access to a clear, readily accessible and convenient process to  
16 request a step therapy exception determination. An insurer may  
17 use its existing medical exceptions process in accordance with  
18 the provisions of Subsections D through I of this section to  
19 satisfy this requirement. The process shall be made easily  
20 accessible for insureds and practitioners on the insurer's  
21 publicly accessible website.

22 D. An insurer shall expeditiously grant an  
23 exception to the health insurance policy's, health care plan's  
24 or certificate of insurance's step therapy protocol, based on  
25 medical necessity and a clinically valid explanation from the

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1 patient's prescribing practitioner as to why a drug on the  
2 health insurance policy's, health care plan's or certificate of  
3 insurance's formulary that is therapeutically equivalent to the  
4 prescribed drug should not be substituted for the prescribed  
5 drug, if:

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

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

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

24 (4) the prescription drug required pursuant to  
25 the step therapy protocol is not in the best interest of the

1 patient, based on clinical appropriateness, because the  
2 patient's use of the prescription drug is expected to:

3 (a) cause a significant barrier to the  
4 patient's adherence to or compliance with the patient's plan of  
5 care;

6 (b) worsen a comorbid condition of the  
7 patient; or

8 (c) decrease the patient's ability to  
9 achieve or maintain reasonable functional ability in performing  
10 daily activities.

11 E. Upon the granting of an exception to a health  
12 insurance policy's, health care plan's or certificate of  
13 insurance's step therapy protocol, an insurer shall authorize  
14 continuing coverage for the life of the insured for the  
15 prescription drug that is the subject of the exception request.

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

24 G. An insurer's denial of a request for an  
25 exception for step therapy protocols shall be subject to review

1 and appeal pursuant to the Patient Protection Act.

2 H. After an insured has made an exception request  
3 in accordance with the provisions of this section, an insurer  
4 shall authorize continued coverage of a prescription drug that  
5 is the subject of the exception request pending the  
6 determination of the exception request.

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

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

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

17 J. The provisions of this section shall apply only  
18 to a health insurance policy, health care plan or certificate  
19 of insurance delivered, issued for delivery or renewed on or  
20 after January 1, 2025.

21 K. The superintendent shall promulgate rules as may  
22 be necessary to appropriately implement the provisions of this  
23 section.

24 L. Nothing in this section shall be interpreted to  
25 interfere with the superintendent's authority to regulate



underscored material = new  
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1 prescription drug coverage benefits under other state and  
2 federal law.

3 M. As used in this section, "medical necessity" or  
4 "medically necessary" means health care services determined by  
5 a practitioner, in consultation with the insurer, to be  
6 appropriate or necessary, according to:

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

9 (2) practice guidelines developed by the  
10 federal government or national or professional medical  
11 societies, boards or associations; or

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

18 SECTION 6. A new section of the Health Maintenance  
19 Organization Law is enacted to read:

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

22 A. Each individual or group health maintenance  
23 organization contract delivered or issued for delivery in this  
24 state that provides a prescription drug benefit for which any  
25 step therapy protocols are required shall establish clinical

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

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

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

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

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

25 (b) explains the relationship between

1 treatment options and outcomes;

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

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

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

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

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

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

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1 explanation from the patient's prescribing practitioner as to  
2 why a drug on the health maintenance organization contract's  
3 formulary that is therapeutically equivalent to the prescribed  
4 drug should not be substituted for the prescribed 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 maintenance organization contract, or under the enrollee's  
15 previous health coverage, the enrollee has tried the  
16 prescription drug that is the subject of the exception request  
17 or another prescription drug in the same pharmacologic class or  
18 with the same mechanism of action as the prescription drug that  
19 is the subject of the exception request and that prescription  
20 drug was discontinued due to lack of efficacy or effectiveness,  
21 diminished effect or an adverse event; or

22 (4) the prescription drug required pursuant to  
23 the step therapy protocol is not in the best interest of the  
24 patient, based on clinical appropriateness, because the  
25 patient's use of the prescription drug is expected to:

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1 (a) cause a significant barrier to the  
2 patient's adherence to or compliance with the patient's plan of  
3 care;

4 (b) worsen a comorbid condition of the  
5 patient; or

6 (c) decrease the patient's ability to  
7 achieve or maintain reasonable functional ability in performing  
8 daily activities.

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

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

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

25 H. After an enrollee has made an exception request

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1 in accordance with the provisions of this section, a carrier  
2 shall authorize continued coverage of a prescription drug that  
3 is the subject of the exception request pending the  
4 determination of the exception request.

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

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

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

14 J. The provisions of this section shall apply only  
15 to a health maintenance organization contract delivered, issued  
16 for delivery or renewed on or after January 1, 2025.

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

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

24 M. As used in this section, "medical necessity" or  
25 "medically necessary" means health care services determined by

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1 a practitioner, in consultation with the carrier, to be  
2 appropriate or necessary, according to:

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

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

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

14 SECTION 7. A new section of the Nonprofit Health Care  
15 Plan Law is enacted to read:

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

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

24 (1) recommend that the prescription drugs  
25 subject to step therapy protocols be taken in the specific

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1 sequence required by the step therapy protocol;

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

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

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

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



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

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

25 (1) the prescription drug that is the subject

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1 of the exception request is contraindicated or will likely  
2 cause an adverse reaction by or physical or mental harm to the  
3 patient;

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

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

17 (4) the prescription drug required pursuant to  
18 the step therapy protocol is not in the best interest of the  
19 patient, based on clinical appropriateness, because the  
20 patient's use of the prescription drug is expected to:

21 (a) cause a significant barrier to the  
22 patient's adherence to or compliance with the patient's plan of  
23 care;

24 (b) worsen a comorbid condition of the  
25 patient; or

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1 (c) decrease the patient's ability to  
2 achieve or maintain reasonable functional ability in performing  
3 daily activities.

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 continuing coverage for the lifetime of the  
7 subscriber for the prescription drug that is the subject of the  
8 exception request.

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

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

20 H. After a subscriber has made an exception request  
21 in accordance with the provisions of this section, a health  
22 care plan shall authorize continued coverage of a prescription  
23 drug that is the subject of the exception request pending the  
24 determination of the exception request.

25 I. The provisions of this section shall not be

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1 construed to prevent:

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

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

9 J. The provisions of this section shall apply only  
10 to a health care plan delivered, issued for delivery or renewed  
11 on or after January 1, 2025.

12 K. The superintendent shall promulgate rules as may  
13 be necessary to appropriately implement the provisions of this  
14 section.

15 L. Nothing in this section shall be interpreted to  
16 interfere with the superintendent's authority to regulate  
17 prescription drug coverage benefits under other state and  
18 federal law.

19 M. As used in this section, "medical necessity" or  
20 "medically necessary" means health care services determined by  
21 a practitioner, in consultation with the health care plan, to  
22 be appropriate or necessary, according to:

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

25 (2) practice guidelines developed by the

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1 federal government or national or professional medical  
2 societies, boards or associations; or

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

10 SECTION 8. EXCEPTIONS.--The provisions of Section 1 and  
11 Sections 3 through 7 of this 2024 act do not apply to  
12 short-term plans subject to the Short-Term Health Plan and  
13 Excepted Benefit Act.

14 SECTION 9. COMPLIANCE.--Beginning in July 2026, and  
15 annually thereafter, the office of superintendent of insurance  
16 or a contracting party shall perform an audit to ensure  
17 compliance with the provisions of this 2024 act.

18 SECTION 10. APPLICABILITY.--The provisions of this act  
19 apply to group health insurance policies, health care plans or  
20 certificates of health insurance, other than small group health  
21 plans, that are delivered, issued for delivery or renewed in  
22 this state on or after January 1, 2025.