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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establish clinical review criteria for those step therapy protocols. The clinical review criteria shall be based on clinical practice guidelines that:

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

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

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

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

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

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

(a) minimizes bias and conflicts of interest;

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

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

(d) considers relevant patient subgroups and preferences; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"[NEW MATERIAL] MEDICAL ASSISTANCE--PRESCRIPTION DRUG

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

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

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

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

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

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

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

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

(a) minimizes bias and conflicts of interest;

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

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

(d) considers relevant patient subgroups and preferences; and

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

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

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

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

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

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

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

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

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diminished effect or an adverse event; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) minimizes bias and conflicts of interest;

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

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

(d) considers relevant patient subgroups and preferences; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

J. The provisions of this section shall apply only

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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facilitating consensus;

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

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

(a) minimizes bias and conflicts of interest;

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

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

(d) considers relevant patient subgroups and preferences; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) minimizes bias and conflicts of interest;

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

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

(d) considers relevant patient subgroups and preferences; and

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

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

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

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

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

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

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

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

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diminished effect or an adverse event; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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appropriate or necessary, according to:

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

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

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

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

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

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

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

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

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

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

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

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

(a) minimizes bias and conflicts of interest;

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

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

(d) considers relevant patient subgroups and preferences; and

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

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

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

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

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

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

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

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

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

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

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subject of the exception request.

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

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

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

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

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

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

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medically necessary.

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

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

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

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

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

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

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

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[bracketed material] = delete

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