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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2019

AN ACT

RELATING TO INSURANCE - ACCIDENT AND SICKNESS INSURANCE POLICIES - STEP THERAPY PROTOCOLS

Introduced By: Senators Gallo, Conley, Goodwin, Lawson, and Pearson

Date Introduced: April 04, 2019

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness
2 Insurance Policies" is hereby amended by adding thereto the following section:

3 **27-18-85. Step therapy protocol.**

4 (a) As used in this section the following words shall, unless the context clearly requires
5 otherwise, have the following meanings:

6 (1) "Clinical practice guidelines" means a systematically developed statement to assist
7 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

8 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,
9 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
10 organization to determine the medical necessity and appropriateness of health care services.

11 (3) "Step therapy exception" means a process that provides that a step therapy protocol
12 should be overridden in favor of immediate coverage of the health care provider's selected
13 prescription drug.

14 (4) "Step therapy protocol" means a protocol or program that establishes the specific
15 sequence in which prescription drugs for a specified medical condition that are medically
16 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
17 self-administered and physician-administered drugs, are covered by an insurer or health plan.

18 (5) "Utilization review organization" means an entity that conducts utilization review,

1 other than a health carrier performing utilization review for its own health benefit plans.

2 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or
3 renewed within the state that provides coverage for prescription drugs and uses step therapy
4 protocols shall have the following requirements and restrictions:

5 (1) Clinical review criteria used to establish step therapy protocols shall be based on
6 clinical practice guidelines:

7 (i) Independently developed by a multidisciplinary panel with expertise in the medical
8 condition, or conditions, for which coverage decisions said criteria will be applied; and

9 (ii) That recommend drugs be taken in the specific sequence required by the step therapy
10 protocol.

11 (c) When coverage of medications for the treatment of any medical condition are
12 restricted for use by an insurer, health plan, or utilization review organization via a step therapy
13 protocol, the patient and prescribing practitioner shall have access to a clear and convenient
14 process to request a step therapy exception. An insurer, health plan, or utilization review
15 organization shall use its existing medical exceptions process to satisfy this requirement. The
16 process shall be disclosed to the patient and health care providers, including documenting and
17 making easily accessible on the insurer's, health plan's or utilization review organization's
18 website.

19 (d) A step therapy override exception shall be expeditiously granted if:

20 (1) The required drug is contraindicated or will likely cause an adverse reaction, or
21 physical or mental harm to the patient;

22 (2) The required prescription drug is expected to be ineffective based on the known
23 clinical characteristics of the patient and the known characteristics of the prescription drug
24 regimen;

25 (3) The enrollee has tried the step therapy-required drug while under their current health
26 plan, or another drug in the same pharmacologic class or with the same mechanism of action and
27 such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an
28 adverse event;

29 (4) The patient is stable on a drug recommended by their health care provider for the
30 medical condition under consideration while on a current or previous health insurance or health
31 benefit plan and no generic substitution is available. This subsection shall not be construed to
32 allow the use of a pharmaceutical sample to meet the requirements for a step therapy override
33 exception.

34 (e) Upon the granting of a step therapy override exception request, the insurer, health

1 plan, utilization review organization, or other entity shall authorize coverage for the drug
2 prescribed by the enrollee's treating health care provider, provided such drug is a covered drug
3 under such terms of policy or contract.
4 (f) The insurer, health plan, or utilization review organization shall grant or deny a step
5 therapy exception request or an appeal within seventy-two (72) hours of receipt. In cases where
6 exigent circumstances exist an insurer, health plan, or utilization review organization shall grant
7 or deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt.
8 Should a grant or denial by an insurer, health plan, or utilization review organization not be
9 received within the time allotted, the exception or appeal shall be deemed granted.
10 (g) Any step therapy exception as defined by this subsection shall be eligible for appeal
11 by an insured.
12 (h) This section shall not be construed to prevent:
13 (1) An insurer, health plan, or utilization review organization from requiring an enrollee
14 to try an AB-rated generic equivalent prior to providing reimbursement for the equivalent
15 branded drug;
16 (2) A health care provider from prescribing a drug they determine is medically
17 appropriate.
18 SECTION 2. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service
19 Corporations" is hereby amended by adding thereto the following section:
20 **27-19-77. Step therapy protocol.**
21 (a) As used in this section the following words shall, unless the context clearly requires
22 otherwise, have the following meanings:
23 (1) "Clinical practice guidelines" means a systematically developed statement to assist
24 practitioner and patient decisions about appropriate health care for specific clinical circumstances.
25 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,
26 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
27 organization to determine the medical necessity and appropriateness of health care services.
28 (3) "Step therapy exception" means a process that provides that a step therapy protocol
29 should be overridden in favor of immediate coverage of the health care provider's selected
30 prescription drug.
31 (4) "Step therapy protocol" means a protocol or program that establishes the specific
32 sequence in which prescription drugs for a specified medical condition that are medically
33 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
34 self-administered and physician-administered drugs, are covered by an insurer or health plan.

1 (5) "Utilization review organization" means an entity that conducts utilization review,
2 other than a health carrier performing utilization review for its own health benefit plans.
3 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or
4 renewed within the state that provides coverage for prescription drugs and uses step therapy
5 protocols shall have the following requirements and restrictions:
6 (1) Clinical review criteria used to establish step therapy protocols shall be based on
7 clinical practice guidelines:
8 (i) Independently developed by a multidisciplinary panel with expertise in the medical
9 condition, or conditions, for which coverage decisions said criteria will be applied; and
10 (ii) That recommend drugs be taken in the specific sequence required by the step therapy
11 protocol.
12 (c) When coverage of medications for the treatment of any medical condition are
13 restricted for use by an insurer, health plan, or utilization review organization via a step therapy
14 protocol, the patient and prescribing practitioner shall have access to a clear and convenient
15 process to request a step therapy exception. An insurer, health plan, or utilization review
16 organization shall use its existing medical exceptions process to satisfy this requirement. The
17 process shall be disclosed to the patient and health care providers, including documenting and
18 making easily accessible on the insurer's, health plan's or utilization review organization's
19 website.
20 (d) A step therapy override exception shall be expeditiously granted if:
21 (1) The required drug is contraindicated or will likely cause an adverse reaction, or
22 physical or mental harm to the patient;
23 (2) The required prescription drug is expected to be ineffective based on the known
24 clinical characteristics of the patient and the known characteristics of the prescription drug
25 regimen;
26 (3) The enrollee has tried the step therapy-required drug while under their current health
27 plan, or another drug in the same pharmacologic class or with the same mechanism of action and
28 such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an
29 adverse event;
30 (4) The patient is stable on a drug recommended by their health care provider for the
31 medical condition under consideration while on a current or previous health insurance or health
32 benefit plan and no generic substitution is available. This subsection shall not be construed to
33 allow the use of a pharmaceutical sample to meet the requirements for a step therapy override
34 exception.

(e) Upon the granting of a step therapy override exception request, the insurer, health plan, utilization review organization, or other entity shall authorize coverage for the drug prescribed by the enrollee's treating health care provider, provided such drug is a covered drug under such terms of policy or contract.

(f) The insurer, health plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within seventy-two (72) hours of receipt. In cases where exigent circumstances exist an insurer, health plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt. Should a grant or denial by an insurer, health plan, or utilization review organization not be received within the time allotted, the exception or appeal shall be deemed granted.

(g) Any step therapy exception as defined by this subsection shall be eligible for appeal by an insured.

(h) This section shall not be construed to prevent:

(1) An insurer, health plan, or utilization review organization from requiring an enrollee to try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

(2) A health care provider from prescribing a drug they determine is medically appropriate.

SECTION 3. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service Corporations" is hereby amended by adding thereto the following section:

27-20-73. Step therapy protocol.

(a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:

(1) "Clinical practice guidelines" means a systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

(2) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer, health plan, or utilization review organization to determine the medical necessity and appropriateness of health care services.

(3) "Step therapy exception" means a process that provides that a step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

(4) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a particular patient and are covered as a pharmacy or medical benefit, including

1 self-administered and physician-administered drugs, are covered by an insurer or health plan.

2 (5) "Utilization review organization" means an entity that conducts utilization review,

3 other than a health carrier performing utilization review for its own health benefit plans.

4 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or

5 renewed within the state that provides coverage for prescription drugs and uses step therapy

6 protocols shall have the following requirements and restrictions:

7 (1) Clinical review criteria used to establish step therapy protocols shall be based on

8 clinical practice guidelines:

9 (i) Independently developed by a multidisciplinary panel with expertise in the medical

10 condition, or conditions, for which coverage decisions said criteria will be applied; and

11 (ii) That recommend drugs be taken in the specific sequence required by the step therapy

12 protocol.

13 (c) When coverage of medications for the treatment of any medical condition are

14 restricted for use by an insurer, health plan, or utilization review organization via a step therapy

15 protocol, the patient and prescribing practitioner shall have access to a clear and convenient

16 process to request a step therapy exception. An insurer, health plan, or utilization review

17 organization shall use its existing medical exceptions process to satisfy this requirement. The

18 process shall be disclosed to the patient and health care providers, including documenting and

19 making easily accessible on the insurer's, health plan's or utilization review organization's

20 website.

21 (d) A step therapy override exception shall be expeditiously granted if:

22 (1) The required drug is contraindicated or will likely cause an adverse reaction, or

23 physical or mental harm to the patient;

24 (2) The required prescription drug is expected to be ineffective based on the known

25 clinical characteristics of the patient and the known characteristics of the prescription drug

26 regimen;

27 (3) The enrollee has tried the step therapy-required drug while under their current health

28 plan, or another drug in the same pharmacologic class or with the same mechanism of action and

29 such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an

30 adverse event;

31 (4) The patient is stable on a drug recommended by their health care provider for the

32 medical condition under consideration while on a current or previous health insurance or health

33 benefit plan and no generic substitution is available. This subsection shall not be construed to

34 allow the use of a pharmaceutical sample to meet the requirements for a step therapy override

exception.

(e) Upon the granting of a step therapy override exception request, the insurer, health plan, utilization review organization, or other entity shall authorize coverage for the drug prescribed by the enrollee's treating health care provider, provided such drug is a covered drug under such terms of policy or contract.

(f) The insurer, health plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within seventy-two (72) hours of receipt. In cases where exigent circumstances exist an insurer, health plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt. Should a grant or denial by an insurer, health plan, or utilization review organization not be received within the time allotted, the exception or appeal shall be deemed granted.

(g) Any step therapy exception as defined by this subsection shall be eligible for appeal by an insured.

(h) This section shall not be construed to prevent:

(1) An insurer, health plan, or utilization review organization from requiring an enrollee to try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

(2) A health care provider from prescribing a drug they determine is medically appropriate.

SECTION 4. Chapter 27-41 of the General Laws entitled "Health Maintenance Organizations" is hereby amended by adding thereto the following section:

27-41-90. Step therapy protocol.

(a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:

(1) "Clinical practice guidelines" means a systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

(2) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer, health plan, or utilization review organization to determine the medical necessity and appropriateness of health care services.

(3) "Step therapy exception" means a process that provides that a step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

(4) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition that are medically

appropriate for a particular patient and are covered as a pharmacy or medical benefit, including self-administered and physician-administered drugs, are covered by an insurer or health plan.

(5) "Utilization review organization" means an entity that conducts utilization review, other than a health carrier performing utilization review for its own health benefit plans.

(b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the state that provides coverage for prescription drugs and uses step therapy protocols shall have the following requirements and restrictions:

(1) Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines:

(i) Independently developed by a multidisciplinary panel with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and

(ii) That recommend drugs be taken in the specific sequence required by the step therapy protocol.

(c) When coverage of medications for the treatment of any medical condition are restricted for use by an insurer, health plan, or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear and convenient process to request a step therapy exception. An insurer, health plan, or utilization review organization shall use its existing medical exceptions process to satisfy this requirement. The process shall be disclosed to the patient and health care providers, including documenting and making easily accessible on the insurer's, health plan's or utilization review organization's website.

(d) A step therapy override exception shall be expeditiously granted if:

(1) The required drug is contraindicated or will likely cause an adverse reaction, or physical or mental harm to the patient;

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

(3) The enrollee has tried the step therapy-required drug while under their current health plan, or another drug in the same pharmacologic class or with the same mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan and no generic substitution is available. This subsection shall not be construed to

allow the use of a pharmaceutical sample to meet the requirements for a step therapy override exception.

(e) Upon the granting of a step therapy override exception request, the insurer, health plan, utilization review organization, or other entity shall authorize coverage for the drug prescribed by the enrollee's treating health care provider, provided such drug is a covered drug under such terms of policy or contract.

(f) The insurer, health plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within seventy-two (72) hours of receipt. In cases where exigent circumstances exist an insurer, health plan, or utilization review organization shall grant or deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt. Should a grant or denial by an insurer, health plan, or utilization review organization not be received within the time allotted, the exception or appeal shall be deemed granted.

(g) Any step therapy exception as defined by this subsection shall be eligible for appeal by an insured.

(h) This section shall not be construed to prevent:

(1) An insurer, health plan, or utilization review organization from requiring an enrollee to try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

(2) A health care provider from prescribing a drug they determine is medically appropriate.

SECTION 5. This act shall take effect upon passage and shall apply only to health insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2020.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO INSURANCE - ACCIDENT AND SICKNESS INSURANCE POLICIES - STEP THERAPY PROTOCOLS

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1 This act would require health insurers, nonprofit hospital service corporations, nonprofit
2 medical service corporations and health maintenance organizations that issue policies that provide
3 coverage for prescription drugs and use step therapy protocols, to base step therapy protocols on
4 appropriate clinical practice guidelines or published peer review data developed by independent
5 experts with knowledge of the condition or conditions under consideration; that patients be
6 exempt from step therapy protocols when inappropriate; and that patients have access to a fair,
7 transparent and independent process for requesting an exception to a step therapy protocol when
8 the patient's physician deems appropriate.
9 This act would take effect upon passage and shall apply only to health insurance and
10 health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2020.

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