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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2017

A N A C T

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

Introduced By: Senators Gallo, Goodwin, Miller, and Satchell

Date Introduced: May 04, 2017

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 **27-18-83. 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 protocol" means a protocol or program that establishes the specific
12 sequence in which prescription drugs for a specified medical condition that are medically
13 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
14 self-administered and physician-administered drugs, are covered by an insurer or health plan.
15 (4) "Step therapy override determination" means a determination as to whether step
16 therapy should apply in a particular situation, or whether the step therapy protocol should be
17 overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This
18 determination is based on a review of the patient's and/or prescriber's request for an override,

1 along with supporting rationale and documentation.

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 determination. An insurer, health plan, or utilization

17 review organization may use its existing medical exceptions process to satisfy this requirement.

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

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

20 website.

21 (d) A step therapy override exception determination request shall be expeditiously

22 considered if:

23 (1) The required drug is contraindicated;

24 (2) The enrollee has tried the step therapy-required drug while under their current or a

25 previous health plan, or another drug in the same pharmacologic class or with the same

26 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,

27 diminished effect, or an adverse event;

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

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

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

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

32 exception.

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

34 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) This section shall not be construed to prevent:

(1) An insurer, health plan, or utilization review organization from requiring an enrollee 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 2. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service Corporations" is hereby amended by adding thereto the following section:

27-19-74. 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 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.

(4) "Step therapy override determination" means a determination as to whether step therapy should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This determination is based on a review of the patient's and/or prescriber's request for an override, along with supporting rationale and documentation.

(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 determination. An insurer, health plan, or utilization review organization may 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 determination request shall be expeditiously considered if:

(1) The required drug is contraindicated;

(2) The enrollee has tried the step therapy-required drug while under their current or a previous 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;

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

(1) An insurer, health plan, or utilization review organization from requiring an enrollee 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.

1 SECTION 3. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service
2 Corporations" is hereby amended by adding thereto the following section:
3 **27-20-70. 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 protocol" means a protocol or program that establishes the specific
12 sequence in which prescription drugs for a specified medical condition that are medically
13 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
14 self-administered and physician-administered drugs, are covered by an insurer or health plan.
15 (4) "Step therapy override determination" means a determination as to whether step
16 therapy should apply in a particular situation, or whether the step therapy protocol should be
17 overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This
18 determination is based on a review of the patient's and/or prescriber's request for an override,
19 along with supporting rationale and documentation.
20 (5) "Utilization review organization" means an entity that conducts utilization review,
21 other than a health carrier performing utilization review for its own health benefit plans.
22 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or
23 renewed within the state that provides coverage for prescription drugs and uses step therapy
24 protocols shall have the following requirements and restrictions:
25 (1) Clinical review criteria used to establish step therapy protocols shall be based on
26 clinical practice guidelines:
27 (i) Independently developed by a multidisciplinary panel with expertise in the medical
28 condition, or conditions, for which coverage decisions said criteria will be applied; and
29 (ii) That recommend drugs be taken in the specific sequence required by the step therapy
30 protocol.
31 (c) When coverage of medications for the treatment of any medical condition are
32 restricted for use by an insurer, health plan, or utilization review organization via a step therapy
33 protocol, the patient and prescribing practitioner shall have access to a clear and convenient
34 process to request a step therapy exception determination. An insurer, health plan, or utilization

review organization may 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 determination request shall be expeditiously considered if:

(1) The required drug is contraindicated;

(2) The enrollee has tried the step therapy-required drug while under their current or a previous 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;

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

(1) An insurer, health plan, or utilization review organization from requiring an enrollee 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:

27-41-87. 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,

1 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
2 organization to determine the medical necessity and appropriateness of health care services.
3 (3) "Step therapy protocol" means a protocol or program that establishes the specific
4 sequence in which prescription drugs for a specified medical condition that are medically
5 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including
6 self-administered and physician-administered drugs, are covered by an insurer or health plan.
7 (4) "Step therapy override determination" means a determination as to whether step
8 therapy should apply in a particular situation, or whether the step therapy protocol should be
9 overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This
10 determination is based on a review of the patient's and/or prescriber's request for an override,
11 along with supporting rationale and documentation.
12 (5) "Utilization review organization" means an entity that conducts utilization review,
13 other than a health carrier performing utilization review for its own health benefit plans.
14 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or
15 renewed within the state that provides coverage for prescription drugs and uses step therapy
16 protocols shall have the following requirements and restrictions:
17 (1) Clinical review criteria used to establish step therapy protocols shall be based on
18 clinical practice guidelines:
19 (i) Independently developed by a multidisciplinary panel with expertise in the medical
20 condition, or conditions, for which coverage decisions said criteria will be applied; and
21 (ii) That recommend drugs be taken in the specific sequence required by the step therapy
22 protocol.
23 (c) When coverage of medications for the treatment of any medical condition are
24 restricted for use by an insurer, health plan, or utilization review organization via a step therapy
25 protocol, the patient and prescribing practitioner shall have access to a clear and convenient
26 process to request a step therapy exception determination. An insurer, health plan, or utilization
27 review organization may use its existing medical exceptions process to satisfy this requirement.
28 The process shall be disclosed to the patient and health care providers, including documenting
29 and making easily accessible on the insurer's, health plan's or utilization review organization's
30 website.
31 (d) A step therapy override exception determination request shall be expeditiously
32 considered if:
33 (1) The required drug is contraindicated;
34 (2) The enrollee has tried the step therapy-required drug while under their current or a

1 previous health plan, or another drug in the same pharmacologic class or with the same
2 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
3 diminished effect, or an adverse event;
4 (3) The patient is stable on a drug recommended by their health care provider for the
5 medical condition under consideration while on a current or previous health insurance or health
6 benefit plan and no generic substitution is available. This subsection shall not be construed to
7 allow the use of a pharmaceutical sample to meet the requirements for a step therapy override
8 exception.
9 (e) Upon the granting of a step therapy override exception Request, the insurer, health
10 plan, utilization review organization, or other entity shall authorize coverage for the drug
11 prescribed by the enrollee's treating health care provider, provided such drug is a covered drug
12 under such terms of policy or contract.
13 (f) This section shall not be construed to prevent:
14 (1) An insurer, health plan, or utilization review organization from requiring an enrollee
15 try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
16 drug;
17 (2) A health care provider from prescribing a drug they determine is medically
18 appropriate.
19 SECTION 5. This act shall take effect upon passage and shall apply only to health
20 insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1,
21 2018.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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

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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 patients physician deems appropriate.
9 This act would take effect upon passage and would apply only to health insurance and
10 health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2018.

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