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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2021

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A N A C T

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

Introduced By: Senators Gallo, and Lombardo

Date Introduced: February 18, 2021

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 Insurance
2 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, other

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

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

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

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

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

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

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

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

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

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

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

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

14 (i) The health insurance commissioner may promulgate such rules and regulations,
15 including rules and regulations under chapter 18.9 of title 27, the benefit determination and
16 utilization review act, as are necessary and proper to effectuate the purpose and for the efficient
17 administration and enforcement of this section entitled "step therapy protocol", as well as to
18 effectuate the coordination of the efficient administration and enforcement of this section with the
19 act.

20 SECTION 2. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service
21 Corporations" is hereby amended by adding thereto the following section:

22 **27-19-77. Step therapy protocol.**

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

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

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

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

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

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

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

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

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

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

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

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

24 (2) The required prescription drug is expected to be ineffective based on the known clinical
25 characteristics of the patient and the known characteristics of the prescription drug 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 allow
33 the use of a pharmaceutical sample to meet the requirements for a step therapy override exception.

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

1 utilization review organization, or other entity shall authorize coverage for the drug prescribed by
2 the enrollee's treating health care provider, provided such drug is a covered drug under such terms
3 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 or
7 deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt. Should
8 a grant or denial by an insurer, health plan, or utilization review organization not be received within
9 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 by
11 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 to
14 try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
15 drug;

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

17 (i) The health insurance commissioner may promulgate such rules and regulations,
18 including rules and regulations under chapter 18.9 of title 27, the benefit determination and
19 utilization review act, as are necessary and proper to effectuate the purpose and for the efficient
20 administration and enforcement of this section entitled "step therapy protocol", as well as to
21 effectuate the coordination of the efficient administration and enforcement of this section with the
22 act.

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

25 **27-20-73. Step therapy protocol.**

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

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

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

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

1 prescription drug.

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

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

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

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

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

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

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

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

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

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

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

33 (4) The patient is stable on a drug recommended by their health care provider for the
34 medical condition under consideration while on a current or previous health insurance or health

1 benefit plan and no generic substitution is available. This subsection shall not be construed to allow
2 the use of a pharmaceutical sample to meet the requirements for a step therapy override exception.

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

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

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

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

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

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

20 (i) The health insurance commissioner may promulgate such rules and regulations,
21 including rules and regulations under chapter 18.9 of title 27, the benefit determination and
22 utilization review act, as are necessary and proper to effectuate the purpose and for the efficient
23 administration and enforcement of this section entitled "step therapy protocol", as well as to
24 effectuate the coordination of the efficient administration and enforcement of this section with the
25 act.

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

28 **27-41-90. Step therapy protocol.**

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

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

33 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,
34 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review

1 organization to determine the medical necessity and appropriateness of health care services.

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

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

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

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

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

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

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

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

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

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

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

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

1 adverse event:

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

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

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

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

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

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

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

23 (i) The health insurance commissioner may promulgate such rules and regulations,
24 including rules and regulations under chapter 18.9 of title 27, the benefit determination and
25 utilization review act, as are necessary and proper to effectuate the purpose and for the efficient
26 administration and enforcement of this section entitled "step therapy protocol", as well as to
27 effectuate the coordination of the efficient administration and enforcement of this section with the
28 act.

29 SECTION 5. This act shall take effect upon passage and shall apply only to health
30 insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1,
31 2022.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T

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

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 exempt
6 from step therapy protocols when inappropriate; and that patients have access to a fair, transparent
7 and independent process for requesting an exception to a step therapy protocol when the patient's
8 physician deems appropriate.

9 This act would take effect upon passage and shall apply only to health insurance and health
10 benefit plans delivered, issued for delivery, or renewed on or after January 1, 2022.

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