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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2018

A N A C T

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

Introduced By: Representatives McKiernan, Almeida, Perez, Winfield, and Fogarty

Date Introduced: May 30, 2018

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

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

27-18-84. 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 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.

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

27-19-76. 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 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.

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

27-20-72. 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 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.

(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 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 granted 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:

27-41-89. 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 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.

(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 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 granted 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 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, 2019.

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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 PROTOCOL

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This act would require health insurers, nonprofit hospital service corporations, nonprofit medical service corporations and health maintenance organizations that issue policies that provide coverage for prescription drugs and use step therapy protocols, to base step therapy protocols on appropriate clinical practice guidelines or published peer review data developed by independent experts with knowledge of the condition or conditions under consideration; that patients be exempt from step therapy protocols when inappropriate; and that patients have access to a fair, transparent and independent process for requesting an exception to a step therapy protocol when the patients physician deems appropriate.

This act would take effect upon passage and would apply only to health insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2019.

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