CHAPTER 44
FORMERLY
HOUSE SUBSTITUTE NO. 1
FOR
HOUSE BILL NO. 105

AN ACT TO AMEND TITLE 18 OF THE DELAWARE CODE RELATING TO HEALTH INSURANCE CONTRACTS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

WHEREAS, health insurance plans increasingly use step therapy protocols under which patients are required to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider; and

WHEREAS, such step therapy protocols, where they are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, can play an important role in controlling health care costs; and

WHEREAS, however, in some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who may either not realize a benefit from taking a prescription drug or may suffer harm from taking an inappropriate drug; and

WHEREAS, without uniform policies in Delaware for step therapy protocols, all patients may not receive the equivalent or most appropriate treatment; and

WHEREAS, it is imperative that step therapy protocols in Delaware preserve the heath care provider's right to make treatment decisions in the best interest of the patient; and

WHEREAS, it is a matter of public interest that health insurers be required 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 or otherwise not in the best interest of the patients; and that patients have access to a fair, transparent and independent process for requesting an exception to a step therapy protocol when the patient's physician deems appropriate.

NOW, THEREFORE:

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 33, of Title 18, of the Delaware Code by making deletions as shown by strike through, insertions as shown by underline and redesignating as follows:

§ 3371 Definitions.

In this section, the following words have the meanings indicated:

(11) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient are covered by an insurer or health plan.

(12) “Step therapy exception determination” means a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider’s selected prescription drug. This determination is based on a review of the request for an override, along with supporting rationale and documentation.

~~(11)~~ (13) "Utilization review entity" means an individual or entity which performs pre-authorization or step therapy protocol review for 1 or more of the following entities:

a. An employer with employees who are covered under a health-benefit plan or health-insurance policy or contract issued for delivery in this State or delivered in this State which does not fall under the Employee Retirement Income Security Act (ERISA) [29 U.S.C. § 1001 et seq.];

b. An insurer, health-benefit plan, or health-service corporation that writes health-insurance policies, performs pre-authorization, performs step therapy protocol review or an entity to which these capabilities have been delegated;

c. A preferred-provider organization, managed-care organization, or health-maintenance organization;

d. Any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits to a person treated by a health-care provider in Delaware under a policy, plan, or contract;

e. This definition does not include accident-only, credit, dental, vision, long-term care or disability income insurance, coverage issued as a supplement to liability insurance, worker's compensation, ~~or~~ similar insurance or automobile medical payment insurance, or any coverage under state or federal governmental plans.

§3381. Step Therapy Exception Process.

(a) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by an insurer, health plan, or utilization review entity through the use of a step therapy protocol, the patient and prescribing practitioner shall have access to a clear, readily accessible and convenient process to request a step therapy exception determination. An insurer, health service corporation, health plan, or utilization review entity may use its existing medical exceptions process to satisfy this requirement. The process shall be made easily accessible via the insurer’s, health plan’s, or utilization review entity’s website. A step therapy exception determination shall be expeditiously granted in any one of the following circumstances:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction by 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 patient has tried the required prescription drug while under the patient’s current or previous health insurance or health benefit plan, or another prescription drug in the same pharmacologic class or with the

same mechanism of action, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) The required prescription drug is not in the best interest of the patient, based on medical necessity.

(5) The patient is stable, for the medical condition under consideration, on a prescription drug prescribed by the patient's health care provider or while the patient was insured by the patient's current or a previous insurance or health benefit plan.

(b) The insurer, health services corporation, health plan, or utilization review entity shall grant or deny a step therapy exception request, which shall be from a health care provider, and which shall state the circumstance which qualifies the patient for a step therapy exception pursuant to §3381(a), within 2 business days of receipt of such request. A step therapy exception determination not granted or denied in writing at the end of 2 days shall be deemed granted.

(1) During a step therapy exception determination under (a)(5) of this section, a determination will be deemed granted until the insurer, health services corporation, health plan, or utilization review entity issues a step therapy exception determination.

(c) In cases where emergency circumstances exist, as outlined in §3349 of this Title, an insurer, health plan, or utilization review entity shall grant or deny a step therapy exception request within twenty-four (24) hours of receipt of a request, which shall be from a health care provider, and which shall state the circumstance which qualifies the patient for a step therapy exception pursuant to §3381(a). A request shall be deemed granted if the required response is not received by the requesting or appealing party within the times set forth in this subsection.

(d) Upon the granting of a step therapy exception determination, the insurer, health plan, or utilization review entity shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

(e) This section shall not be construed to prevent any of the following:

(1) An insurer, health plan, or utilization review entity from requiring a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded prescription drug.

(2) A health care provider from prescribing a prescription drug that is determined to be medically necessary.

(f) Clinical criteria used to establish a step therapy protocol shall be based on clinical criteria that:

(1) Recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol.

(2) Developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

a. Requiring members to disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers and recuse themselves of voting if they have a conflict of interest.

b. Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus.

(3) Offer opportunities for public review and comments.

(4) Based on peer reviewed studies, research, and medical practice.

(5) Created by an explicit and transparent process that:

a. Minimizes biases and conflicts of interest.

b. Explains the relationship between treatment options and outcomes.

c. Rates the quality of the evidence supporting recommendations.

d. Considers relevant patient subgroups and preferences.

e. Continually updated through a review of new evidence, research and newly developed treatments.

(6) When establishing a step therapy protocol, a utilization review entity shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical criteria.

(7) This section shall not be construed to require insurers, health plans or the state to set up a new entity to develop clinical review criteria used for step therapy protocols.

(g) Any step therapy exception determination as defined by this subsection shall be eligible for appeal by an insured or their authorized representative, as outlined in Chapter 3 and Chapter 64 of this Title.

Section 2. Amend Chapter 35, of Title 18, of the Delaware Code by making deletions as shown by strike through, insertions as shown by underline and redesignating as follows:

§ 3571 Definitions.

In this section, the following words have the meanings indicated:

(11) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient are covered by an insurer or health plan.

(12) "Step therapy exception determination" means a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug. This determination is based on a review of the request for an override, along with supporting rationale and documentation.

~~(11)~~ (13) "Utilization review entity" means an individual or entity which performs pre-authorization or step therapy protocol review for 1 or more of the following entities:

a. An employer with employees who are covered under a health-benefit plan or health-insurance policy or contract issued for delivery in this State or delivered in this State which does not fall under the Employee Retirement Income Security Act (ERISA) [29 U.S.C. § 1001 et seq.];

b. An insurer, health-benefit plan, or health-service corporation that writes health-insurance policies, performs pre-authorization, performs step therapy protocol review or an entity to which these capabilities have been delegated;

c. A preferred-provider organization, managed-care organization, or health-maintenance organization;

d. Any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits to a person treated by a health-care provider in Delaware under a policy, plan, or contract;

e. This definition does not include accident-only, credit, dental, vision, long-term care or disability income insurance, coverage issued as a supplement to liability insurance, worker's compensation or similar insurance or automobile medical payment insurance, or any coverage under state or federal governmental plans.

§3591. Step Therapy Exception Process.

(a) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by an insurer, health plan, or utilization review entity through the use of a step therapy protocol, the patient and prescribing practitioner shall have access to a clear, readily accessible and convenient process to request a step therapy exception determination. An insurer, health service corporation, health plan, or utilization review entity may use its existing medical exceptions process to satisfy this requirement. The process shall be made easily accessible via the insurer's, health plan's, or utilization review entity's website. A step therapy exception determination shall be expeditiously granted in any one of the following circumstances:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction by 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 patient has tried the required prescription drug while under the patient's current or previous health insurance or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) The required prescription drug is not in the best interest of the patient, based on medical necessity.

(5) The patient is stable, for the medical condition under consideration, on a prescription drug selected by the patient's health care provider or while the patient was insured by the patient's current or a previous insurance or health benefit plan.

(b) The insurer, health services corporation, health plan, or utilization review entity shall grant or deny a step therapy exception request within 2 business days of receipt of such request, which shall be from a health care provider, and which shall state the circumstance which qualifies the patient for a step therapy exception pursuant to §3591(a). A step therapy exception determination not granted or denied in writing at the end of 2 days shall be deemed granted.

(1) During a step therapy exception determination under paragraph (a)(5) of this section, a determination will be deemed granted until the insurer, health services corporation, health plan, or utilization review entity issues a step therapy exception determination.

(c) In cases where emergency circumstances exist, as outlined in § 3565 of this Title, an insurer, health plan, or utilization review entity shall grant or deny a step therapy exception request within twenty-four (24) hours of receipt

of a request, which shall be from a health care provider, and which shall state the circumstance which qualifies the patient for a step therapy exception pursuant to §3591(a). A request shall be deemed granted if the required response is not received by the requesting or appealing party within the times set forth in this subsection.

(d) Upon the granting of a step therapy exception determination, the insurer, health plan, or utilization review entity shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

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

(1) An insurer, health plan, or utilization review entity from requiring a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded prescription drug.

(2) A health care provider from prescribing a prescription drug that is determined to be medically necessary.

(f) Clinical criteria used to establish a step therapy protocol shall be based on clinical criteria that:

(1) Recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol.

(2) Developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

a. Requiring members to disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers and recuse themselves of voting if they have a conflict of interest.

b. Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus.

(3) Offer opportunities for public review and comments.

(4) Based on peer reviewed studies, research, and medical practice.

(5) Created by an explicit and transparent process that:

a. Minimizes biases and conflicts of interest.

b. Explains the relationship between treatment options and outcomes.

c. Rates the quality of the evidence supporting recommendations.

d. Considers relevant patient subgroups and preferences.

e. Continually updated through a review of new evidence, research and newly developed treatments.

(6) When establishing a step therapy protocol, a utilization review entity shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical criteria.

(7) This section shall not be construed to require insurers, health plans or the state to set up a new entity to develop clinical review criteria used for step therapy protocols.

(g) Any step therapy exception determination as defined by this subsection shall be eligible for appeal by an insured or their authorized representative, as outlined in Chapter 3 and Chapter 64 of this Title.

Section 3. Effective date

This Act shall take effect 9 months following its enactment into law, and shall apply to all individual and group health insurance policies, contracts, or certificates that are issued or renewed in this State on or after the effective date of the Act.

Approved June 18, 2019