SENATE . . . . . No. 2843

The Commonwealth of Massachusetts

In the One Hundred and Ninety-First General Court
(2019-2020)

SENATE, July 30, 2020.

The committee on Senate Ways and Means to whom was referred the Senate Bill relative to step therapy and patient safety (Senate, No. 2433), - reports, recommending that the same ought to pass with an amendment substituting a new draft with the same title (Senate, No. 2843).

For the committee,
Michael J. Rodrigues

FILED ON: 7/27/2020

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In the One Hundred and Ninety-First General Court
(2019-2020)

An Act relative to step therapy and patient safety.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 118E of the General Laws is hereby amended by inserting after section 10M the following section:-

Section 10N. (a) For the purposes of this section, the following terms shall have the following meanings unless the context clearly requires otherwise:

"Clinical review criteria", shall have the same meaning as defined in section 1 of chapter 176O.

"Step therapy exception", shall have the same meaning as defined in section 12A of chapter 176O.

"Step therapy protocol", a protocol, policy or program that establishes the specific sequence in which prescription drugs for a specified medical condition are covered by MassHealth or a managed care organization or utilization review organization contracted with MassHealth.

"Utilization review organization", shall have the same meaning as defined in section 1 of chapter 176O.

(b)(1) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by MassHealth directly or through a managed care organization, a utilization review organization or other entity contracted with MassHealth to provide coverage to or manage benefits for enrollees, through the use of a step therapy protocol, a request for exception from such requirements shall be expeditiously granted if:

(i) the prescription drug required under the step therapy protocol is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the enrollee;

(ii) the prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics of the prescription drug regimen;

(iii) the enrollee has tried the prescription drug required under the step therapy protocol while covered under MassHealth, a managed care organization, a utilization review organization or other entity contracted with MassHealth, a previous health insurance or a 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;

(iv) the prescription drug required under the step therapy protocol is not in the best interest of the enrollee as determined by the prescriber, based on medical necessity, as defined by regulations governing MassHealth coverage or reimbursement; or

(v) the enrollee is stable on a prescription drug selected by their health care provider, as attested to in documentation submitted by the health care provider, for the medical condition under consideration while covered under MassHealth, a managed care organization, utilization review organization or other entity contracted with MassHealth or a previous health insurance or health benefit plan and that switching drugs will likely cause an adverse reaction by or physical or mental harm to the enrollee; provided, however, that in such instances, MassHealth, a managed care organization, a utilization review organization or other entity contracted with MassHealth shall have a continuity of coverage policy in place to ensure that the enrollee does not experience any delay in accessing the drug, including a drug administered by infusion, while the exception request is being reviewed; provided further, that MassHealth shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to drugs covered by MassHealth.

(2) Upon granting a step therapy exception under this section, MassHealth, a managed care organization, a utilization review organization or other entity contracted with MassHealth shall authorize coverage for the prescription drug prescribed by the enrollee's treating health care provider.

(3) A MassHealth, managed care organization or utilization review organization contracted with MassHealth review process for step therapy exception requests shall meet the requirements set forth in section 1927(d)(5)(A) of the federal Social Security Act.

(4) Nothing in this section shall prevent: (i) a pharmacist from effecting substitutions of prescription drugs consistent with of section 12D of chapter 112; or (ii) a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

SECTION 2. Chapter 176O of the General Laws is hereby amended by inserting after section 12 the following 2 sections:-

Section 12A. (a) For the purposes of this section, the following terms shall have the following meanings unless the context clearly requires otherwise:

"Step therapy protocol", a protocol, policy, or program that establishes the specific sequence in which prescription drugs for a specified medical condition are covered by a carrier.

"Step therapy exception", a step therapy protocol that should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

(b)(1) Clinical review criteria used to establish a step therapy protocol shall not require an insured to utilize a medication that is not likely to be clinically effective for the prescribed purpose, based on peer-reviewed clinical evidence, in order to obtain coverage for a prescribed medication. Any requirement to utilize a medication other than that prescribed shall be subject to the processes in subsection (c) to ensure an insured's access to a prescription drug that is likely to be clinically effective for that insured's individual clinical circumstances.

(2) When establishing clinical review criteria to be used for a step therapy protocol, a carrier or a utilization review organization shall take into account the needs of atypical patient populations and diagnoses.

(3) This section shall not require a carrier or a utilization review organization to set up a new entity to develop clinical review criteria used for step therapy protocols.

(c)(1) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a carrier directly or through a utilization review organization through the use

of a step therapy protocol, the insured and prescribing health care provider shall have access to a clear, readily accessible and convenient process to request a step therapy exception. A carrier or a utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process shall be made easily accessible on the website of a carrier or a utilization review organization.

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

(i) the prescription drug required under the step therapy protocol is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the insured;

(ii) the prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics of the prescription drug regimen;

(iii) the insured or prescribing health care provider has provided documentation to the carrier or utilization review organization establishing that the insured has previously tried the prescription drug required under the step therapy protocol, 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;

(iv) the prescription drug required under the step therapy protocol is not in the best interest of the insured, as determined by the prescriber, based on medical necessity; or

(v) the insured or prescribing health care provider has provided documentation to a carrier or utilization review organization establishing that the insured is stable on a prescription drug selected by their health care provider for the medical condition under consideration while

on a current or previous health insurance or health benefit plan and that switching drugs will likely cause an adverse reaction by or physical or mental harm to the insured; provided, however, that in such instances, the carrier or utilization review organization shall have a continuity of coverage policy in place to ensure that the insured does not experience any delay in accessing the drug, including a drug administered by infusion, while the exception request is being reviewed; provided further, that the continuity of coverage policy shall include, but not be limited to, a 30-day fill of a United States Food and Drug Administration approved drug reimbursed through a pharmacy benefit that the insured has already been prescribed and on which the insured is stable; and provided further, that a carrier shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to drugs covered by the plan.

(d) Upon granting a step therapy exception, a carrier or utilization review organization shall authorize coverage for the prescription drug prescribed by the insured's treating health care provider.

(e) A carrier or a utilization review organization shall grant or deny a step therapy exception request or an appeal not more than 72 hours following the receipt of all necessary information to establish the medical necessity of the prescribed treatment. If additional delay would result in significant risk to the insured's health or well-being, a carrier or a utilization review organization shall respond not more than 24 hours following the receipt of all necessary information to establish the medical necessity of the prescribed treatment. If a response by a carrier or a utilization review organization is not received within the time required under this paragraph, the step therapy exception request or appeal shall be deemed granted.

(f) This section shall apply to carriers that provide coverage of a prescription drug pursuant to a policy that meets the definition of a medication step therapy protocol, regardless of whether the policy is described as a step therapy protocol.

(g) Any denial of a step therapy exception shall be eligible for appeal by an insured.

(h) Notwithstanding any law to the contrary, the division shall promulgate regulations necessary to implement this section.

(i) Annually, a carrier or a utilization review organization shall report to the division, in a format prescribed by the division: (i) the number of step therapy exception requests received by exception; (ii) the type of health care providers or the medical specialties of the health care providers submitting step therapy exception requests; (iii) the number of step therapy exception requests by exception that were denied and the reasons for the denials; (iv) the number of step therapy exception requests by exception that were approved; (v) the medical conditions for which patients are granted exceptions due to the likelihood that switching from the prescription drug will likely cause an adverse reaction by or physical or mental harm to the insured; (vi) the number of step therapy exception requests by exception that were initially denied and then appealed; and (vii) the number of step therapy exception requests by exception that were initially denied and then subsequently reversed by internal appeals or external reviews.

Section 12B. There shall be a commission on step therapy protocols within the division. The commission shall consist of: the commissioner of insurance or a designee, who shall serve as chair; the executive director of the health policy commission or a designee; the assistant secretary for MassHealth or a designee; the executive director of the Center for Health Information and Analysis or a designee; and 7 members appointed by the governor, 1 of whom

shall represent the Massachusetts Public Health Association, 1 of whom shall represent Blue Cross Blue Shield of Massachusetts, Inc., 1 of whom shall represent the Massachusetts Association of Health Plans, Inc., 1 of whom shall represent a patient advocacy organization, 1 of whom shall represent an employer organization, 1 of whom shall be currently practicing as a licensed physician in the commonwealth and 1 of whom shall be currently practicing as a licensed clinician, other than a physician, who has prescribing authority under the scope of licensure.

The commission on step therapy protocol shall study and assess the implementation of step therapy process reforms enacted pursuant to section 10N of chapter 118E and section 12A. The commission shall: (i) analyze the impact of step therapy protocols on total medical expenses, health care quality outcomes, premium cost and out-of-pocket costs to the consumer and the health care cost benchmark; and (ii) assess the efficacy of the step therapy exception process in ensuring that consumers diagnosed with medical conditions that rely on stability or have achieved a positive clinical response on a medication are able to maintain that course of treatment, such as a form of multiple sclerosis. The study shall also examine any available empirical data on the impact of step therapy protocols on health disparities related to outcomes, access and medication adherence.

The commission shall meet as needed to meet the reporting requirements of this section.

Not later than October 1 of each even-numbered year, the commission on step therapy protocols shall submit a report that includes findings from the commission's review along with recommendations and any suggested legislation to implement those recommendations to the secretary of health and human services and the joint committee on health care financing.

SECTION 3. Notwithstanding section 12B of chapter 176O of the General Laws, the step therapy commission established under said section 12B of said chapter 176O shall convene its first meeting not later than 90 days from the effective date of this act and provide its first report not later than October 1, 2022.

SECTION 4. Section 1 shall take effect on January 1, 2022.

SECTION 5. Section 12A of chapter 176O of the General Laws shall apply to health benefit plans delivered, issued for delivery, or renewed after January 1, 2022.