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HOUSE . . . . . No. 5358

Text of a further amendment, offered by Mr. Lawn of Watertown, to the Senate amendment (striking out all after the enacting clause and inserting in place thereof the text contained in Senate document numbered 3056) of the House Bill relative to step therapy and patient safety (House, No. 4929). October 20, 2022.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court
(2021-2022)

By striking out all after the enacting clause and inserting in place thereof the following:-

SECTION 1. Chapter 118E of the General Laws is hereby amended by inserting after section 51 the following section:-

Section 51A. (a) For the purposes of this section, the following words shall, unless the context clearly requires otherwise, have the following meanings:-

"Clinical review criteria", as defined in section 1 of chapter 176O.

"Step therapy protocol", a utilization management policy or program that establishes the specific sequence in which a prescription drug for a specified medical condition is covered by the division or an entity with which the division contracts to provide or manage health insurance benefits.

"Utilization review organization", as defined in section 1 of chapter 176O.

(b)(1) Clinical review criteria used to establish a step therapy protocol shall not require an enrollee to utilize a medication that is not likely to be clinically effective for the prescribed

purpose, based on peer-reviewed clinical evidence, in order for the enrollee to obtain coverage for a prescribed medication. Any requirement imposed by the division or an entity with which the division contracts to provide or manage health insurance benefits or by a utilization review organization to utilize a medication other than that prescribed shall permit the enrollee to seek an exception pursuant to subsection (c).

(2) When establishing clinical review criteria to be used for a step therapy protocol, the division or an entity with which the division contracts to provide or manage health insurance benefits or a utilization review organization shall take into account the needs of atypical patient populations and diagnoses.

(3) This section shall not require the division or an entity with which the division contracts to provide or manage health insurance benefits or a utilization review organization to establish a new entity to develop clinical review criteria used for step therapy protocols.

(c)(1) If coverage of a prescription drug for the treatment of any medical condition is restricted for use directly by the division or an entity with which the division contracts to provide or manage health insurance benefits or through a utilization review organization through the use of a step therapy protocol, an enrollee and their prescribing health care provider shall have access to a clear, readily accessible and convenient process to request an exception to such step therapy protocol. An enrollee or their prescribing health care provider may request an exception to such protocol, and such request for an exception shall be granted if any of the following conditions are satisfied: (i) the prescription drug required under the step therapy protocol is contraindicated or will likely cause an adverse reaction in 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 or prescribing health care provider: (A) has provided documentation to the division or an entity with which the division contracts to provide or manage health insurance benefits for the enrollee, or a utilization review organization establishing that the enrollee 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, while covered by the division or an entity with which the division contracts to provide or manage health insurance benefits or by a previous health insurance carrier or a health benefit plan; and (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; (iv) the enrollee or prescribing health care provider has provided documentation to the division or an entity with which the division contracts to provide or manage health insurance benefits for the enrollee, or a utilization review organization establishing that the enrollee: (A) is stable on a prescription drug prescribed by the health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the enrollee.

(2) The division or an entity with which the division contracts to provide or manage health insurance benefits shall have a continuity of coverage policy in place to ensure that the enrollee does not experience any delay in accessing the drug prescribed by their health care provider, including a drug administered by infusion, while the exception request is being reviewed; provided, however, that the division or an entity with which the division contracts to provide or manage health insurance benefits shall not apply any greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to other covered prescription drugs.

(3) Upon granting an exception to the step therapy protocol pursuant to this section, the division or an entity with which the division contracts to provide health insurance benefits shall authorize coverage for the prescription drug prescribed by the enrollee's health care provider. A denial of an exception shall be eligible for appeal by an enrollee.

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

(d) The division or an entity with which the division contracts to provide health insurance benefits or a utilization review organization shall grant or deny a request for an exception to the step therapy protocol or a request to appeal a denial of an exception not more than 3 business days 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 enrollee's health or well-being, the division or an entity with which the division contracts to provide health insurance benefits 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 the division or an entity with which the division contracts to provide health insurance benefits or a utilization review organization is not received within the time required under this paragraph, an exception to the step therapy protocol shall be deemed granted.

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

(f) The division shall promulgate regulations necessary to implement this section.

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 term shall have the following meanings unless the context clearly requires otherwise:

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

(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 imposed by a carrier or utilization review organization to utilize a medication other than that prescribed shall permit the insured to seek an exception to the step therapy protocol pursuant to subsection (c).

(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 establish a new entity to develop clinical review criteria used for step therapy protocols.

(c)(1) If 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 an exception to such step therapy protocol. An insured or their prescribing health care provider may request an exception to such protocol, and such request for an exception shall be granted if: (i) the prescription drug required under the step therapy protocol is contraindicated or will likely cause an adverse reaction in 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) (A) 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 (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the insured or prescribing health care provider has provided documentation to a carrier or utilization review organization establishing that the insured: (A) is stable on a prescription drug prescribed by their health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical or mental harm to the insured.

(2) All carriers shall have a continuity of coverage policy in place to ensure that the insured does not experience any delay in accessing the drug prescribed by their health care provider, including a drug administered by infusion, while the exception request is being reviewed; provided, however, 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.

(3) Upon granting an exception to the step therapy protocol, a carrier or utilization review organization shall authorize coverage for the prescription drug prescribed by the insured's health care provider. A denial of an exception shall be eligible for appeal by an insured.

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

(d) A carrier or a utilization review organization shall grant or deny a request for an exception to the step therapy protocol or a request to appeal a denial of an exception not more than 3 business days 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, an exception to the step therapy protocol shall be deemed granted.

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

(f) The division shall promulgate regulations necessary to implement this section.

(g) Annually, each carrier 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 in 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. (a) 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 and 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 their

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

(b) The commission shall study and assess the implementation of step therapy process reforms established in section 51A 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 including, but not limited to, a form of multiple sclerosis. The commission shall also examine any available empirical data on the impact of step therapy protocols on health disparities related to outcomes, access and medication adherence.

(c) Not later than October 1 of each even-numbered year, the commission shall submit a report that includes findings from the commission's review and recommendations, including any draft legislation necessary to implement the recommendations, to the secretary of health and human services and the joint committee on health care financing.

SECTION 3. Notwithstanding any general or special laws to the contrary, the regulations required pursuant to section 12A of chapter 176O of the General Laws, inserted by section 2, shall be promulgated by the division of insurance not later than 120 days after the effective date of this act.

SECTION 4. The commission on step therapy protocols established under section 12B of chapter 176O of the General Laws, inserted by section 2, shall convene its first meeting not more

than 180 days after the effective date of this act and provide its first report not later than December 31, 2023.

SECTION 5. Section 12A of chapter 176O of the General Laws, inserted by section 2, shall apply to health benefit plans delivered, issued for delivery, or renewed after October 1, 2023.

SECTION 6. Section 1 shall take effect on October 1, 2023.