STATE OF NEW YORK

901--A

2023-2024 Regular Sessions

IN ASSEMBLY

January 11, 2023

Introduced by M. of A. McDONALD, STECK, STIRPE, SANTABARBARA, THIELE, HEVESI, BURDICK, BEEPHAN, NORRIS, K. BROWN, COLTON, BENDETT, GUNTHER, PAULIN, SEAWRIGHT, LEVENBERG, LAVINE, LUNSFORD, ARDILA, COOK, REYES, MEEKS, SAYEGH, JACOBSON, SIMPSON, DAVILA, LUPARDO, SIMON, GALLAHAN, RAGA -- Multi-Sponsored by -- M. of A. EPSTEIN -- read once and referred to the Committee on Insurance -- recommitted to the Committee on Insurance in accordance with Assembly Rule 3, sec. 2 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the insurance law and the public health law, in relation to requiring a utilization review agent to follow certain rules when establishing a step therapy protocol

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Subsection (a) of section 4902 of the insurance law is amended by adding two new paragraphs 15 and 16 to read as follows:

(15) When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol cannot:

(i) require a prescription drug that has not been approved by the United States Food and Drug Administration for the medical condition being treated and/or is not supported by current evidence-based guidelines for the medical condition being treated;

(ii) require an insured to try and fail on more than two drugs within one therapeutic category before providing coverage to the insured for the prescribed drug;

(iii) require the use of a step therapy-required drug for longer than thirty days or a duration of treatment supported by current evidence-based treatment guidelines appropriate to the specific disease state being treated;

(iv) be imposed on an insured if a therapeutic equivalent to the prescribed drug is not available, or if the health plan has documenta-

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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tion that it has covered the drug for the enrollee within the past three hundred sixty-five days;

(v) require a newly enrolled insured to repeat step therapy for a prescribed drug where that insured already completed step therapy for that drug under a prior plan, so long as the enrollee or provider submits information demonstrating completion of a step therapy protocol of the prior plan within the past three hundred sixty-five days; and

(vi) be imposed on an insured for a prescribed drug that was previously approved for coverage by a plan for a specific medical condition after the insured's plan implements a formulary change or utilization management that impacts the coverage criteria for the prescribed drug until the approved override expires, unless a specifically identified and current evidence-based safety concern exists and a different therapeutic alternative drug exists.

(16) When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any written or electronic attestation submitted by the insured's health care professional as defined in section four thousand nine hundred of this title stating that a required drug has failed as prima facie evidence that the required drug has failed.

§ 2. Subsections (c-3) and (g) of section 4903 of the insurance law, subsection (c-3) as added and subsection (g) as amended by chapter 512 of the laws of 2016, are amended to read as follows:

(c-3) Upon a determination that the step therapy protocol should be overridden, the health plan shall authorize immediate coverage for the prescription drug prescribed by the insured's treating health care professional. Any approval of a step therapy protocol override determination request shall be honored until the lesser of either treatment duration based on current evidence-based treatment guidelines or twelve months following the date of the approval of the request or renewal of the insured's coverage.

(g) Failure by the utilization review agent to make a determination within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section four thousand nine hundred four of this title, provided, however, that failure to meet such time periods for a step therapy protocol as defined in subsection (g-9) of section forty-nine hundred of this title or a step therapy protocol override determination pursuant to subsections (c-1), (c-2) and (c-3) of this section shall be deemed to be an override of the step therapy protocol. A utilization review agent's failure to comply with any of the step therapy protocol requirements required in subsections fifteen and sixteen of section four thousand nine hundred two of this title shall be considered a basis for granting an override of the step therapy protocol, absent fraud.

§ 3. Section 4902 of the public health law is amended by adding two new subdivisions 5 and 6 to read as follows:

5. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol cannot:

(a) require a prescription drug that has not been approved by the United States Food and Drug Administration and/or is not supported by current evidence-based guidelines for the medical condition being treated;

(b) require an enrollee to try and fail on more than two drugs within one therapeutic category before providing coverage to the insured for the prescribed drug;

(c) require the use of a step therapy-required drug for longer than thirty days or a duration of treatment supported by current evidence-based treatment guidelines appropriate to the specific disease state being treated;

(d) be imposed on an enrollee if a therapeutic equivalent to the prescribed drug is not available; or if the health plan has documentation that it has covered the drug for the enrollee within the past three hundred sixty-five days;

(e) require a newly enrolled enrollee to repeat step therapy for a prescribed drug where that enrollee already completed step therapy for that drug under a prior plan, so long as the enrollee or provider submit information demonstrating completion of a step therapy protocol of the prior plan within the past three hundred sixty-five days; and

(f) be imposed on an enrollee for a prescribed drug that was previously approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary or utilization management change that impacts the coverage criteria for the prescribed drug until the approved override expires, unless a specifically identified and evidence-based safety concern exists and a different therapeutic alternative drug exists.

6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any written or electronic attestation submitted by the enrollee's health care professional as defined in section forty-nine hundred of this title stating that a required drug has failed as prima facie evidence that the required drug has failed.

§ 4. Subdivisions 3-c and 7 of section 4903 of the public health law, subdivision 3-c as added and subdivision 7 as amended by chapter 512 of the laws of 2016, are amended to read as follows:

3-c. Upon a determination that the step therapy protocol should be overridden, the health plan shall authorize immediate coverage for the prescription drug or drugs prescribed by the enrollee's treating health care professional. Any approval of a step therapy protocol override determination request shall be honored until the lesser of either treatment duration based on current evidence-based treatment guidelines or twelve months following the date of the approval of the request or renewal of the enrollee's coverage.

7. Failure by the utilization review agent to make a determination within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section forty-nine hundred four of this title, provided, however, that failure to meet such time periods for a step therapy protocol as defined in subdivision seven-f-three of section forty-nine hundred of this title or a step therapy protocol override determination pursuant to subdivisions three-a, three-b and three-c of this section shall be deemed to be an override of the step therapy protocol. A utilization review agent's failure to comply with any of the step therapy protocol requirements required in subdivisions five and six of section forty-nine hundred two of this title shall be considered a basis for granting an override of the step therapy protocol, absent fraud.

§ 5. This act shall take effect on the one hundred twentieth day after it shall have become a law.