8191

## IN SENATE

February 1, 2022

- Introduced by Sen. BRESLIN -- read twice and ordered printed, and when printed to be committed to the Committee on Insurance
- 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:

1	Section 1. Subsection (a) of section 4902 of the insurance law is
2	amended by adding two new paragraphs 14 and 15 to read as follows:
3	(14) When establishing a step therapy protocol, a utilization review
4	agent shall ensure that the protocol cannot:
5	(i) require a prescription drug that has not been approved by the
б	United States Food and Drug Administration for the medical condition
7	being treated;
8	(ii) require an insured to try and fail on more than one drug before
9	providing coverage to the insured for the prescribed drug;
10	(iii) require the use of a step therapy-required drug for longer than
11	<u>thirty days;</u>
12	(iv) be imposed on an insured if the insured has taken the prescribed
13	drug covered by the plan within the past three hundred sixty-five days;
14	(v) require a newly enrolled insured to repeat step therapy for a
15	prescribed drug where that insured already completed step therapy for
16	that drug under a prior plan; and
17	(vi) be imposed on an insured for a prescribed drug that was previous-
18	ly approved for coverage by a plan for a specific medical condition
19	after the insured's plan implements a formulary change that impacts the
20	formulary status of the prescribed drug.
21	(15) When establishing a step therapy protocol, a utilization review
22	agent shall ensure that the protocol accepts any attestation submitted
23	by the insured's health care professional as defined in section four
24	thousand nine hundred of this title stating that a required drug has
25	failed as prima facie evidence that the required drug has failed.

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

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2	§ 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
3 4	of the laws of 2016, are amended to read as follows: (c-3) Upon a determination that the step therapy protocol should be
т 5	overridden, the health plan shall authorize immediate coverage for the
6	prescription drug prescribed by the insured's treating health care
7	professional. Any approval of a step therapy protocol override determi-
8	nation request shall be honored until the later of twelve months follow-
9	ing the date of the approval or renewal of the plan.
10	(g) Failure by the utilization review agent to make a determination
11	within the time periods prescribed in this section shall be deemed to be
12	an adverse determination subject to appeal pursuant to section four
13	thousand nine hundred four of this title, provided, however, that fail-
14	ure to meet such time periods for a step therapy protocol as defined in
15	subsection (g-9) of section forty-nine hundred of this title or a step
16	therapy protocol override determination pursuant to subsections (c-1),
17	(c-2) and $(c-3)$ of this section shall be deemed to be an override of the
18	step therapy protocol. <u>A utilization review agent's failure to comply</u>
19	with any of the step therapy protocol requirements required in
20	subsections fourteen and fifteen of section four thousand nine hundred
21	two of this title shall be considered a basis for granting an override
22	of the step therapy protocol.
23	§ 3. Section 4902 of the public health law is amended by adding two
24	new subdivisions 5 and 6 to read as follows:
25	5. When establishing a step therapy protocol, a utilization review
26	agent shall ensure that the protocol cannot:
27	(a) require a prescription drug that has not been approved by the
28	United States Food and Drug Administration for the medical condition
29	being treated;
30	(b) require an enrollee to try and fail on more than one drug before
31	providing coverage to the insured for the prescribed drug;
32	(c) require the use of a step therapy-required drug for longer than
33	the design of the second
	thirty days;
34	(d) be imposed on an enrollee if the enrollee has taken the prescribed
34	(d) be imposed on an enrollee if the enrollee has taken the prescribed
34 35	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) require a newly enrolled enrollee to repeat step therapy for a prescribed drug where that enrollee already completed step therapy for</li> </ul>
34 35 36 37 38	(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days; (f) 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; and
34 35 36 37	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) require a newly enrolled enrollee to repeat step therapy for a prescribed drug where that enrollee already completed step therapy for</li> </ul>
34 35 36 37 38	(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days; (f) 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; and
34 35 36 37 38 39	(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days; (f) 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; and (g) be imposed on an enrollee for a prescribed drug that was previous-
34 35 36 37 38 39 40	(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days; (f) 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; and (g) be imposed on an enrollee for a prescribed drug that was previous- ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.
34 35 36 37 38 39 40 41	(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days; (f) 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; and (g) be imposed on an enrollee for a prescribed drug that was previous- ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug. 6. When establishing a step therapy protocol, a utilization review
34 35 36 37 38 39 40 41 42	(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days; (f) 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; and (g) be imposed on an enrollee for a prescribed drug that was previous- ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug. 6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any attestation submitted
34 35 36 37 38 39 40 41 42 43 44 45	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any attestation submitted by the enrollee's health care professional as defined in section forty-</li> </ul>
34 35 36 37 38 39 40 41 42 43 44 45 46	(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days; (f) 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; and (g) be imposed on an enrollee for a prescribed drug that was previous- ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug. 6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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
34 35 36 37 38 39 40 41 42 43 44 45 46 47	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any attestation submitted by the enrollee's health care professional as defined in section fortynine hundred of this title stating that a required drug has failed as prima facie evidence that the required drug has failed.</li> </ul>
34 35 36 37 38 39 40 41 42 43 44 45 46 47 48	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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.</li> <li>§ 4. Subdivisions 3-c and 7 of section 4903 of the public health law,</li> </ul>
34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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.</li> <li>§ 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</li> </ul>
34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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.</li> <li>§ 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:</li> </ul>
34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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.</li> <li>§ 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:</li> </ul>
34 35 36 37 39 40 41 42 43 44 45 46 47 48 50 51 52	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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.</li> <li>§ 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:</li> <li>3-c. Upon a determination that the step therapy protocol should be overridden, the health plan shall authorize immediate coverage for the</li> </ul>
34 35 36 37 39 40 41 42 43 44 45 46 47 48 951 512 53	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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.</li> <li>§ 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:</li> <li>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</li> </ul>
34 35 36 37 39 40 423 445 467 490 5123 535 54	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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.</li> <li>§ 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:</li> <li>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</li> </ul>
34 35 36 37 39 40 41 42 43 445 46 47 489 501 52 53	<ul> <li>(d) be imposed on an enrollee if the enrollee has taken the prescribed drug covered by the plan within the past three hundred sixty-five days;</li> <li>(f) 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; and</li> <li>(g) be imposed on an enrollee for a prescribed drug that was previous-ly approved for coverage by a plan for a specific medical condition after the enrollee's plan implements a formulary change that impacts the formulary status of the prescribed drug.</li> <li>6. When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any 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.</li> <li>§ 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:</li> <li>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</li> </ul>

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7. Failure by the utilization review agent to make a determination 1 2 within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section forty-3 nine hundred four of this title, provided, however, that failure to meet 4 5 such time periods for a step therapy protocol as defined in subdivision б seven-f-three of section forty-nine hundred of this title or a step protocol 7 therapy override determination pursuant to subdivisions three-a, three-b and three-c of this section shall be deemed to be an 8 9 override of the step therapy protocol. <u>A utilization review agent's</u> 10 failure to comply with any of the step therapy protocol requirements 11 required in subdivisions five and six of section forty-nine hundred two 12 of this title shall be considered a basis for granting an override of 13 the step therapy protocol. § 5. This act shall take effect immediately. 14