

HOUSE No. 4929

HOUSE OF REPRESENTATIVES, June 28, 2022.

The committee on Ways and Means to whom was referred the Bill relative to step therapy and patient safety (House, No. 1311), reports recommending that the same ought to pass with an amendment substituting therefor the accompanying bill (House, No. 4929).

For the committee,

AARON MICHLEWITZ.

FILED ON: 6/28/2022

The Commonwealth of Massachusetts

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

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:

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

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

5 “Clinical review criteria”, as defined in section 1 of chapter 176O.

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

10 “Utilization review organization”, as defined in section 1 of chapter 176O.

11 (b)(1) Clinical review criteria used to establish a step therapy protocol shall not require an
12 enrollee to utilize a medication that is not likely to be clinically effective for the prescribed
13 purpose, based on peer-reviewed clinical evidence, in order for the enrollee to obtain coverage

14 for a prescribed medication. Any requirement imposed by the division or an entity with which
15 the division contracts to provide or manage health insurance benefits, or by a utilization review
16 organization to utilize a medication other than that prescribed shall permit the enrollee to seek an
17 exception pursuant to subsection (c).

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

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

25 (c)(1) When coverage of a prescription drug for the treatment of any medical condition is
26 restricted for use directly by the division or an entity with which the division contracts to provide
27 or manage health insurance benefits, or through a utilization review organization, through the use
28 of a step therapy protocol, an enrollee and their prescribing health care provider shall have access
29 to a clear, readily accessible and convenient process to request an exception to such step therapy
30 protocol. An enrollee or their prescribing health care provider may request an exception to such
31 protocol, and such request for an exception shall be granted if any of the following conditions are
32 satisfied:

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

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

38 (iii) the enrollee or prescribing health care provider: (A) has provided documentation to
39 the division or an entity with which the division contracts to provide or manage health insurance
40 benefits for the enrollee, or a utilization review organization establishing that the enrollee has
41 previously tried the prescription drug required under the step therapy protocol, or another
42 prescription drug in the same pharmacologic class or with the same mechanism of action, while
43 covered by the division or an entity with which the division contracts to provide or manage
44 health insurance benefits, or by a previous health insurance carrier or a health benefit plan, and
45 (B) such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished
46 effect or an adverse event; or

47 (iv) the enrollee or prescribing health care provider has provided documentation to the
48 division or an entity with which the division contracts to provide or manage health insurance
49 benefits for the enrollee, or a utilization review organization establishing that the enrollee (A) is
50 stable on a prescription drug prescribed by the health care provider, and (B) switching drugs will
51 likely cause an adverse reaction in or physical or mental harm to the enrollee.

52 (2) The division or an entity with which the division contracts to provide or manage
53 health insurance benefits shall have a continuity of coverage policy in place to ensure that the
54 enrollee does not experience any delay in accessing the drug prescribed by their health care
55 provider, including a drug administered by infusion, while the exception request is being
56 reviewed; provided, that the division or an entity with which the division contracts to provide or

57 manage health insurance benefits shall not apply any greater deductible, coinsurance,
58 copayments or out-of-pocket limits than would otherwise apply to other covered prescription
59 drugs.

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

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

67 (d) The division or an entity with which the division contracts to provide health insurance
68 benefits or a utilization review organization shall grant or deny a request for an exception to the
69 step therapy protocol or a request to appeal a denial of an exception not more than 3 business
70 days following the receipt of all necessary information to establish the medical necessity of the
71 prescribed treatment. If additional delay would result in significant risk to the enrollee's health or
72 well-being, the division or an entity with which the division contracts to provide health insurance
73 benefits or a utilization review organization shall respond on the next business day following the
74 receipt of all necessary information to establish the medical necessity of the prescribed treatment.
75 If a response by the division or an entity with which the division contracts to provide health
76 insurance benefits or a utilization review organization is not received within the time required
77 under this paragraph, an exception to the step therapy protocol shall be deemed granted.

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

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

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

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

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

89 “Utilization review organization”, as defined in section 1.

90 (b)(1) Clinical review criteria used to establish a step therapy protocol shall not require an
91 insured to utilize a medication that is not likely to be clinically effective for the prescribed
92 purpose, based on peer-reviewed clinical evidence, in order to obtain coverage for a prescribed
93 medication. Any requirement imposed by a carrier or utilization review organization to utilize a
94 medication other than that prescribed shall permit the insured to seek an exception to the step
95 therapy protocol pursuant to subsection (c).

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

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

101 (c)(1) When coverage of a prescription drug for the treatment of any medical condition is
102 restricted for use by a carrier directly or through a utilization review organization through the use
103 of a step therapy protocol, the insured and prescribing health care provider shall have access to a
104 clear, readily accessible and convenient process to request an exception to such step therapy
105 protocol. An insured or their prescribing health care provider may request an exception to such
106 protocol, and such request for an exception shall be granted if any of the following conditions are
107 satisfied:

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

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

113 (iii) the insured or prescribing health care provider (A) has provided documentation to the
114 carrier or utilization review organization establishing that the insured has previously tried the
115 prescription drug required under the step therapy protocol, or another prescription drug in the
116 same pharmacologic class or with the same mechanism of action, and (B) such prescription drug
117 was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event;
118 or

119 (iv) the insured or prescribing health care provider has provided documentation to a
120 carrier or utilization review organization establishing that the insured (A) is stable on a

121 prescription drug prescribed by their health care provider, and (B) switching drugs will likely
122 cause an adverse reaction in or physical or mental harm to the insured;

123 (2) All carriers shall have a continuity of coverage policy in place to ensure that the
124 insured does not experience any delay in accessing the drug prescribed by their health care
125 provider, including a drug administered by infusion, while the exception request is being
126 reviewed; provided, that the continuity of coverage policy shall include, but not be limited to, a
127 30-day fill of a United States Food and Drug Administration-approved drug reimbursed through
128 a pharmacy benefit that the insured has already been prescribed and on which the insured is
129 stable; and provided further, that a carrier shall not apply any greater deductible, coinsurance,
130 copayments or out-of-pocket limits than would otherwise apply to drugs covered by the plan.

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

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

137 (d) A carrier or a utilization review organization shall grant or deny a request for an
138 exception to the step therapy protocol or a request to appeal a denial of an exception not more
139 than 3 business days following the receipt of all necessary information to establish the medical
140 necessity of the prescribed treatment. If additional delay would result in significant risk to the
141 insured's health or well-being, a carrier or a utilization review organization shall respond on the
142 next business day following the receipt of all necessary information to establish the medical

143 necessity of the prescribed treatment. If a response by a carrier or a utilization review
144 organization is not received within the time required under this paragraph, an exception to the
145 step therapy protocol shall be deemed granted.

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

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

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

160 Section 12B. (a) There shall be a commission on step therapy protocols within the
161 division. The commission shall consist of: the commissioner of insurance or a designee, who
162 shall serve as chair; the executive director of the health policy commission or a designee; the
163 assistant secretary for MassHealth or a designee; the executive director of the center for health
164 information and analysis or a designee; and 7 members appointed by the governor, 1 of whom

165 shall represent the Massachusetts Public Health Association, 1 of whom shall represent Blue
166 Cross and Blue Shield of Massachusetts, Inc., 1 of whom shall represent the Massachusetts
167 Association of Health Plans, Inc., 1 of whom shall represent a patient advocacy organization, 1
168 of whom shall represent an employer organization, 1 of whom shall be currently practicing as a
169 licensed physician in the commonwealth and 1 of whom shall be currently practicing as a
170 licensed clinician, other than a physician, who has prescribing authority under the scope of their
171 licensure. The commission shall meet as needed to satisfy the reporting requirements of this
172 section.

173 (b) The commission shall study and assess the implementation of step therapy process
174 reforms established in section 51A of chapter 118E and section 12A. The commission shall: (i)
175 analyze the impact of step therapy protocols on total medical expenses, health care quality
176 outcomes, premium cost and out-of-pocket costs to the consumer and the health care cost
177 benchmark; and (ii) assess the efficacy of the step therapy exception process in ensuring that
178 consumers diagnosed with medical conditions that rely on stability or have achieved a positive
179 clinical response on a medication are able to maintain that course of treatment including, but not
180 limited to, a form of multiple sclerosis. The commission shall also examine any available
181 empirical data on the impact of step therapy protocols on health disparities related to outcomes,
182 access and medication adherence.

183 (c) Not later than October 1 of each even-numbered year, the commission shall submit a
184 report that includes findings from the commission's review along with recommendations and any
185 suggested legislation to implement said recommendations to the secretary of health and human
186 services and the house and senate chairs of the joint committee on health care financing.

187 SECTION 3. Notwithstanding any general or special laws to the contrary, the regulations
188 required pursuant to section 12A of chapter 176O of the General Laws, inserted by section 2,
189 shall be promulgated by the division of insurance not later than 90 days after the effective date of
190 this act.

191 SECTION 4. The commission on step therapy protocols established under section 12B of
192 chapter 176O of the General Laws shall convene its first meeting not later than 180 days after the
193 effective date of this act and provide its first report not later than December 31, 2023.

194 SECTION 5. Section 1 shall take effect on July 1, 2023.

195 SECTION 6. Section 12A of chapter 176O of the General Laws, inserted by section 2,
196 shall apply to health benefit plans delivered, issued for delivery, or renewed after July 1, 2023.