SENATE . . . . No. 3056

The Commonwealth of Massachusetts

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

SENATE, July 26, 2022.

The committee on Senate Ways and Means, to whom was referred the House Bill relative to step therapy and patient safety (House, No. 4929),-- reports, recommending that the same ought to pass with an amendment striking out all after the enacting clause and inserting in place thereof the text of Senate document numbered 3056.

For the committee,
Michael J. Rodrigues

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

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 have the
4 following meanings, unless the context clearly requires otherwise,:-

5 "Clinical review criteria" shall have the same meaning as found in section 1 of chapter
6 176O.

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

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

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

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

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

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

27 (c)(1) If coverage of a prescription drug for the treatment of any medical condition is
28 restricted for use directly by the division or an entity with which the division contracts to provide
29 or manage health insurance benefits or through a utilization review organization through the use
30 of a step therapy protocol, an enrollee and their prescribing health care provider shall have access
31 to a clear, readily accessible and convenient process to request an exception to such step therapy
32 protocol. An enrollee or their prescribing health care provider may request an exception to such
33 protocol, and such request for an exception shall be granted if: (i) the prescription drug required
34 under the step therapy protocol is contraindicated or will likely cause an adverse reaction in or
35 physical or mental harm to the enrollee; (ii) the prescription drug required under the step therapy
36 protocol is expected to be ineffective based on the known clinical characteristics of the enrollee
37 and the known characteristics of the prescription drug regimen; (iii) the enrollee or prescribing

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

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

59 (3) Upon granting an exception to the step therapy protocol pursuant to this section, the
60 division or an entity with which the division contracts to provide health insurance benefits shall

61 authorize coverage for the prescription drug prescribed by the enrollee's health care provider. A
62 denial of an exception shall be eligible for appeal by an enrollee.

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

66 (d) The division or an entity with which the division contracts to provide health insurance
67 benefits or a utilization review organization shall grant or deny a request for an exception to the
68 step therapy protocol or a request to appeal a denial of an exception not more than 72 hours
69 following the receipt of all necessary information to establish the medical necessity of the
70 prescribed treatment. If additional delay would result in significant risk to the enrollee's health or
71 well-being, the division or an entity with which the division contracts to provide health insurance
72 benefits or a utilization review organization shall respond not more than 24 hours following the
73 receipt of all necessary information to establish the medical necessity of the prescribed treatment.
74 If a response by the division or an entity with which the division contracts to provide health
75 insurance benefits or a utilization review organization is not received within the time required
76 under this paragraph, an exception to the step therapy protocol shall be deemed granted.

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

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

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

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

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

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

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

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

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

105 under the step therapy protocol is contraindicated or will likely cause an adverse reaction in or
106 physical or mental harm to the insured; (ii) the prescription drug required under the step therapy
107 protocol is expected to be ineffective based on the known clinical characteristics of the insured
108 and the known characteristics of the prescription drug regimen; (iii) (A) the insured or
109 prescribing health care provider has provided documentation to the carrier or utilization review
110 organization establishing that the insured has previously tried the prescription drug required
111 under the step therapy protocol, or another prescription drug in the same pharmacologic class or
112 with the same mechanism of action,; and (B) such prescription drug was discontinued due to lack
113 of efficacy or effectiveness, diminished effect or an adverse event; or (iv) the insured or
114 prescribing health care provider has provided documentation to a carrier or utilization review
115 organization establishing that the insured: (A) is stable on a prescription drug prescribed by their
116 health care provider; and (B) switching drugs will likely cause an adverse reaction in or physical
117 or mental harm to the insured.

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

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

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

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

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

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

146 (g) Annually, each carrier shall report to the division, in a format prescribed by the
147 division: (i) the number of step therapy exception requests received by exception; (ii) the type of
148 health care providers or the medical specialties of the health care providers submitting step

149 therapy exception requests; (iii) the number of step therapy exception requests by exception that
150 were denied and the reasons for the denials; (iv) the number of step therapy exception requests
151 by exception that were approved; (v) the medical conditions for which patients are granted
152 exceptions due to the likelihood that switching from the prescription drug will likely cause an
153 adverse reaction in or physical or mental harm to the insured; (vi) the number of step therapy
154 exception requests by exception that were initially denied and then appealed; and (vii) the
155 number of step therapy exception requests by exception that were initially denied and then
156 subsequently reversed by internal appeals or external reviews.

157 Section 12B. (a) There shall be a commission on step therapy protocols within the
158 division. The commission shall consist of: the commissioner of insurance or a designee, who
159 shall serve as chair; the executive director of the health policy commission or a designee; the
160 assistant secretary for MassHealth or a designee; the executive director of the center for health
161 information and analysis or a designee; and 7 members appointed by the governor, 1 of whom
162 shall represent the Massachusetts Public Health Association, 1 of whom shall represent Blue
163 Cross and Blue Shield of Massachusetts, Inc., 1 of whom shall represent the Massachusetts
164 Association of Health Plans, Inc., 1 of whom shall represent a patient advocacy organization, 1
165 of whom shall represent an employer organization, 1 of whom shall be currently practicing as a
166 licensed physician in the commonwealth and 1 of whom shall be currently practicing as a
167 licensed clinician, other than a physician, who has prescribing authority under the scope of their
168 licensure. The commission shall meet as needed to satisfy the reporting requirements of this
169 section.

170 (b) The commission shall study and assess the implementation of step therapy process
171 reforms established in section 51A of chapter 118E and section 12A. The commission shall: (i)

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

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

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

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

190 SECTION 5. Section 12A of chapter 176O of the General Laws shall apply to health
191 benefit plans delivered, issued for delivery, or renewed after July 1, 2023.

192 SECTION 6. Section 1 shall take effect on July 1, 2023.