

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:-

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) If 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: (i) the prescription drug required under the step therapy protocol is contraindicated or
33 will likely cause an adverse reaction in or physical or mental harm to the enrollee; (ii) the
34 prescription drug required under the step therapy protocol is expected to be ineffective based on

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

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

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

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

65 (d) The division or an entity with which the division contracts to provide health insurance
66 benefits or a utilization review organization shall grant or deny a request for an exception to the
67 step therapy protocol or a request to appeal a denial of an exception not more than 3 business
68 days following the receipt of all necessary information to establish the medical necessity of the
69 prescribed treatment. If additional delay would result in significant risk to the enrollee's health or
70 well-being, the division or an entity with which the division contracts to provide health insurance
71 benefits or a utilization review organization shall respond not more than 24 hours following the
72 receipt of all necessary information to establish the medical necessity of the prescribed treatment.
73 If a response by the division or an entity with which the division contracts to provide health
74 insurance benefits or a utilization review organization is not received within the time required
75 under this paragraph, an exception to the step therapy protocol shall be deemed granted.

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

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

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

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

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

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

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

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

98 (c)(1) If coverage of a prescription drug for the treatment of any medical condition is
99 restricted for use by a carrier directly or through a utilization review organization through the use
100 of a step therapy protocol, the insured and prescribing health care provider shall have access to a

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

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

124 deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply to drugs
125 covered by the plan.

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

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

132 (d) A carrier or a utilization review organization shall grant or deny a request for an
133 exception to the step therapy protocol or a request to appeal a denial of an exception not more
134 than 3 business days following the receipt of all necessary information to establish the medical
135 necessity of the prescribed treatment. If additional delay would result in significant risk to the
136 insured's health or well-being, a carrier or a utilization review organization shall respond not
137 more than 24 hours following the receipt of all necessary information to establish the medical
138 necessity of the prescribed treatment. If a response by a carrier or a utilization review
139 organization is not received within the time required under this paragraph, an exception to the
140 step therapy protocol shall be deemed granted.

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

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

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

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

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

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

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

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

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

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

191 SECTION 5. Section 12A of chapter 176O of the General Laws, inserted by section 2,
192 shall apply to health benefit plans delivered, issued for delivery, or renewed after October 1,
193 2023.

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