

HOUSE No. 1311

The Commonwealth of Massachusetts

PRESENTED BY:

Jeffrey N. Roy and Marjorie C. Decker

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to step therapy and patient safety.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Jeffrey N. Roy</i>	<i>10th Norfolk</i>	<i>1/26/2021</i>
<i>Marjorie C. Decker</i>	<i>25th Middlesex</i>	<i>2/10/2021</i>
<i>Ruth B. Balsler</i>	<i>12th Middlesex</i>	<i>2/19/2021</i>
<i>Elizabeth A. Malia</i>	<i>11th Suffolk</i>	<i>2/24/2021</i>
<i>Tram T. Nguyen</i>	<i>18th Essex</i>	<i>2/26/2021</i>
<i>Patrick M. O'Connor</i>	<i>Plymouth and Norfolk</i>	<i>2/26/2021</i>
<i>Lindsay N. Sabadosa</i>	<i>1st Hampshire</i>	<i>2/26/2021</i>
<i>Jack Patrick Lewis</i>	<i>7th Middlesex</i>	<i>2/26/2021</i>
<i>Brian W. Murray</i>	<i>10th Worcester</i>	<i>2/26/2021</i>
<i>Tricia Farley-Bouvier</i>	<i>3rd Berkshire</i>	<i>2/26/2021</i>
<i>Patrick Joseph Kearney</i>	<i>4th Plymouth</i>	<i>2/26/2021</i>
<i>Michael S. Day</i>	<i>31st Middlesex</i>	<i>2/27/2021</i>
<i>Carmine Lawrence Gentile</i>	<i>13th Middlesex</i>	<i>3/2/2021</i>
<i>Kelly W. Pease</i>	<i>4th Hampden</i>	<i>3/10/2021</i>
<i>John Barrett, III</i>	<i>1st Berkshire</i>	<i>3/10/2021</i>
<i>Thomas A. Golden, Jr.</i>	<i>16th Middlesex</i>	<i>3/10/2021</i>
<i>Paul F. Tucker</i>	<i>7th Essex</i>	<i>3/10/2021</i>
<i>Steven S. Howitt</i>	<i>4th Bristol</i>	<i>3/10/2021</i>

<i>Danielle W. Gregoire</i>	<i>4th Middlesex</i>	<i>3/10/2021</i>
<i>Hannah Kane</i>	<i>11th Worcester</i>	<i>3/10/2021</i>
<i>Joseph W. McGonagle, Jr.</i>	<i>28th Middlesex</i>	<i>3/10/2021</i>
<i>Carolyn C. Dykema</i>	<i>8th Middlesex</i>	<i>3/10/2021</i>
<i>John J. Lawn, Jr.</i>	<i>10th Middlesex</i>	<i>3/10/2021</i>
<i>Alice Hanlon Peisch</i>	<i>14th Norfolk</i>	<i>3/10/2021</i>
<i>David M. Rogers</i>	<i>24th Middlesex</i>	<i>3/11/2021</i>
<i>Kenneth I. Gordon</i>	<i>21st Middlesex</i>	<i>3/12/2021</i>
<i>Steven Ultrino</i>	<i>33rd Middlesex</i>	<i>3/19/2021</i>
<i>David Allen Robertson</i>	<i>19th Middlesex</i>	<i>3/19/2021</i>
<i>Adam J. Scanlon</i>	<i>14th Bristol</i>	<i>3/19/2021</i>
<i>David Paul Linsky</i>	<i>5th Middlesex</i>	<i>3/19/2021</i>
<i>Edward R. Philips</i>	<i>8th Norfolk</i>	<i>3/24/2021</i>
<i>Vanna Howard</i>	<i>17th Middlesex</i>	<i>3/24/2021</i>
<i>William C. Galvin</i>	<i>6th Norfolk</i>	<i>3/24/2021</i>
<i>Josh S. Cutler</i>	<i>6th Plymouth</i>	<i>3/29/2021</i>
<i>David F. DeCoste</i>	<i>5th Plymouth</i>	<i>3/29/2021</i>
<i>Tami L. Gouveia</i>	<i>14th Middlesex</i>	<i>3/29/2021</i>
<i>Carol A. Doherty</i>	<i>3rd Bristol</i>	<i>3/30/2021</i>
<i>Mark J. Cusack</i>	<i>5th Norfolk</i>	<i>3/30/2021</i>
<i>Thomas M. Stanley</i>	<i>9th Middlesex</i>	<i>3/30/2021</i>

HOUSE No. 1311

By Representatives Roy of Franklin and Decker of Cambridge, a petition (accompanied by bill, House, No. 1311) of Jeffrey N. Roy, Marjorie C. Decker and others relative to step therapy and patient safety. Health Care Financing.

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 10M the following section:-

3 Section 10N. (a) For the purposes of this section, the following terms shall have the
4 following meanings unless the context clearly requires otherwise:

5 “Clinical review criteria”, shall have the same meaning as defined in section 1 of chapter
6 176O.

7 “Step therapy exception”, shall have the same meaning as defined in section 12A of
8 chapter 176O.

9 “Step therapy protocol”, a protocol, policy or program that establishes the specific
10 sequence in which prescription drugs for a specified medical condition are covered by

11 MassHealth or a managed care organization or utilization review organization contracted with
12 MassHealth.

13 “Utilization review organization”, shall have the same meaning as defined in section 1 of
14 chapter 176O.

15 (b)(1) When coverage of a prescription drug for the treatment of any medical condition is
16 restricted for use by MassHealth directly or through a managed care organization, a utilization
17 review organization or other entity contracted with MassHealth to provide coverage to or
18 manage benefits for enrollees, through the use of a step therapy protocol, a request for exception
19 from such requirements shall be expeditiously granted if:

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

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

25 (iii) the enrollee has tried the prescription drug required under the step therapy protocol
26 while covered under MassHealth, a managed care organization, a utilization review organization
27 or other entity contracted with MassHealth, a previous health insurance or a health benefit plan
28 or another prescription drug in the same pharmacologic class or with the same mechanism of
29 action and such prescription drug was discontinued due to lack of efficacy or effectiveness,
30 diminished effect or an adverse event;

31 (iv) the prescription drug required under the step therapy protocol is not in the best
32 interest of the enrollee as determined by the prescriber, based on medical necessity, as defined by
33 regulations governing MassHealth coverage or reimbursement; or

34 (v) the enrollee is stable on a prescription drug selected by their health care provider, as
35 attested to in documentation submitted by the health care provider, for the medical condition
36 under consideration while covered under MassHealth, a managed care organization, utilization
37 review organization or other entity contracted with MassHealth or a previous health insurance or
38 health benefit plan and that switching drugs will likely cause an adverse reaction by or physical
39 or mental harm to the enrollee; provided, however, that in such instances, MassHealth, a
40 managed care organization, a utilization review organization or other entity contracted with
41 MassHealth shall have a continuity of coverage policy in place to ensure that the enrollee does
42 not experience any delay in accessing the drug, including a drug administered by infusion, while
43 the exception request is being reviewed; provided further, that MassHealth shall not apply any
44 greater deductible, coinsurance, copayments or out-of-pocket limits than would otherwise apply
45 to drugs covered by MassHealth.

46 (2) Upon granting a step therapy exception under this section, MassHealth, a managed
47 care organization, a utilization review organization or other entity contracted with MassHealth
48 shall authorize coverage for the prescription drug prescribed by the enrollee's treating health care
49 provider.

50 (3) A MassHealth, managed care organization or utilization review organization
51 contracted with MassHealth review process for step therapy exception requests shall meet the
52 requirements set forth in section 1927(d)(5)(A) of the federal Social Security Act.

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

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

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

60 “Step therapy protocol”, a protocol, policy, or program that establishes the specific
61 sequence in which prescription drugs for a specified medical condition are covered by a carrier.

62 “Step therapy exception”, a step therapy protocol that should be overridden in favor of
63 immediate coverage of the health care provider’s selected prescription drug.

64 (b)(1) Clinical review criteria used to establish a step therapy protocol shall not require an
65 insured to utilize a medication that is not likely to be clinically effective for the prescribed
66 purpose, based on peer-reviewed clinical evidence, in order to obtain coverage for a prescribed
67 medication. Any requirement to utilize a medication other than that prescribed shall be subject to
68 the processes in subsection (c) to ensure an insured’s access to a prescription drug that is likely
69 to be clinically effective for that insured’s individual clinical circumstances.

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

73 (3) This section shall not require a carrier or a utilization review organization to set up a
74 new entity to develop clinical review criteria used for step therapy protocols.

75 (c)(1) When coverage of a prescription drug for the treatment of any medical condition is
76 restricted for use by a carrier directly or through a utilization review organization through the use
77 of a step therapy protocol, the insured and prescribing health care provider shall have access to a
78 clear, readily accessible and convenient process to request a step therapy exception. A carrier or
79 a utilization review organization may use its existing medical exceptions process to satisfy this
80 requirement. The process shall be made easily accessible on the website of a carrier or a
81 utilization review organization.

82 (2) A step therapy exception shall be expeditiously granted if:

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

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

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

93 (iv) the prescription drug required under the step therapy protocol is not in the best
94 interest of the insured, as determined by the prescriber, based on medical necessity; or

95 (v) the insured or prescribing health care provider has provided documentation to a
96 carrier or utilization review organization establishing that the insured is stable on a prescription
97 drug selected by their health care provider for the medical condition under consideration while
98 on a current or previous health insurance or health benefit plan and that switching drugs will
99 likely cause an adverse reaction by or physical or mental harm to the insured; provided, however,
100 that in such instances, the carrier or utilization review organization shall have a continuity of
101 coverage policy in place to ensure that the insured does not experience any delay in accessing the
102 drug, including a drug administered by infusion, while the exception request is being reviewed;
103 provided further, that the continuity of coverage policy shall include, but not be limited to, a 30-
104 day fill of a United States Food and Drug Administration approved drug reimbursed through a
105 pharmacy benefit that the insured has already been prescribed and on which the insured is stable;
106 and provided further, that a carrier shall not apply any greater deductible, coinsurance,
107 copayments or out-of-pocket limits than would otherwise apply to drugs covered by the plan.

108 (d) Upon granting a step therapy exception, a carrier or utilization review organization
109 shall authorize coverage for the prescription drug prescribed by the insured's treating health care
110 provider.

111 (e) A carrier or a utilization review organization shall grant or deny a step therapy
112 exception request or an appeal not more than 72 hours following the receipt of all necessary
113 information to establish the medical necessity of the prescribed treatment. If additional delay
114 would result in significant risk to the insured's health or well-being, a carrier or a utilization

115 review organization shall respond not more than 24 hours following the receipt of all necessary
116 information to establish the medical necessity of the prescribed treatment. If a response by a
117 carrier or a utilization review organization is not received within the time required under this
118 paragraph, the step therapy exception request or appeal shall be deemed granted.

119 (f) This section shall apply to carriers that provide coverage of a prescription drug
120 pursuant to a policy that meets the definition of a medication step therapy protocol, regardless of
121 whether the policy is described as a step therapy protocol.

122 (g) Any denial of a step therapy exception shall be eligible for appeal by an insured.

123 (h) Notwithstanding any law to the contrary, the division shall promulgate regulations
124 necessary to implement this section.

125 (i) Annually, a carrier or a utilization review organization shall report to the division, in a
126 format prescribed by the division: (i) the number of step therapy exception requests received by
127 exception; (ii) the type of health care providers or the medical specialties of the health care
128 providers submitting step therapy exception requests; (iii) the number of step therapy exception
129 requests by exception that were denied and the reasons for the denials; (iv) the number of step
130 therapy exception requests by exception that were approved; (v) the medical conditions for
131 which patients are granted exceptions due to the likelihood that switching from the prescription
132 drug will likely cause an adverse reaction by or physical or mental harm to the insured; (vi) the
133 number of step therapy exception requests by exception that were initially denied and then
134 appealed; and (vii) the number of step therapy exception requests by exception that were initially
135 denied and then subsequently reversed by internal appeals or external reviews.

136 Section 12B. There shall be a commission on step therapy protocols within the division.
137 The commission shall consist of: the commissioner of insurance or a designee, who shall serve as
138 chair; the executive director of the health policy commission or a designee; the assistant
139 secretary for MassHealth or a designee; the executive director of the Center for Health
140 Information and Analysis or a designee; and 7 members appointed by the governor, 1 of whom
141 shall represent the Massachusetts Public Health Association, 1 of whom shall represent Blue
142 Cross Blue Shield of Massachusetts, Inc., 1 of whom shall represent the Massachusetts
143 Association of Health Plans, Inc., 1 of whom shall represent a patient advocacy organization, 1
144 of whom shall represent an employer organization, 1 of whom shall be currently practicing as a
145 licensed physician in the commonwealth and 1 of whom shall be currently practicing as a
146 licensed clinician, other than a physician, who has prescribing authority under the scope of
147 licensure.

148 The commission on step therapy protocol shall study and assess the implementation of
149 step therapy process reforms enacted pursuant to section 10N of chapter 118E and section 12A.
150 The commission shall: (i) analyze the impact of step therapy protocols on total medical expenses,
151 health care quality outcomes, premium cost and out-of-pocket costs to the consumer and the
152 health care cost benchmark; and (ii) assess the efficacy of the step therapy exception process in
153 ensuring that consumers diagnosed with medical conditions that rely on stability or have
154 achieved a positive clinical response on a medication are able to maintain that course of
155 treatment, such as a form of multiple sclerosis. The study shall also examine any available
156 empirical data on the impact of step therapy protocols on health disparities related to outcomes,
157 access and medication adherence.

158 The commission shall meet as needed to meet the reporting requirements of this section.

159 Not later than October 1 of each even-numbered year, the commission on step therapy
160 protocols shall submit a report that includes findings from the commission's review along with
161 recommendations and any suggested legislation to implement those recommendations to the
162 secretary of health and human services and the joint committee on health care financing.

163 SECTION 3. Notwithstanding section 12B of chapter 176O of the General Laws, the step
164 therapy commission established under said section 12B of said chapter 176O shall convene its
165 first meeting not later than 90 days from the effective date of this act and provide its first report
166 not later than October 1, 2023.

167 SECTION 4. Section 1 shall take effect on January 1, 2023.

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