

HOUSE No.

The Commonwealth of Massachusetts

PRESENTED BY:

Jennifer E. Benson

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 fail first and patient safety.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
<i>Jennifer E. Benson</i>	<i>37th Middlesex</i>
<i>Angelo J. Puppolo, Jr.</i>	<i>12th Hampden</i>
<i>Bud L. Williams</i>	<i>11th Hampden</i>
<i>Brian W. Murray</i>	<i>10th Worcester</i>
<i>Claire D. Cronin</i>	<i>11th Plymouth</i>
<i>Louis L. Kafka</i>	<i>8th Norfolk</i>
<i>Kimberly N. Ferguson</i>	<i>1st Worcester</i>
<i>Paul R. Feeney</i>	<i>Bristol and Norfolk</i>
<i>Stephan Hay</i>	<i>3rd Worcester</i>
<i>David Allen Robertson</i>	<i>19th Middlesex</i>
<i>Tram T. Nguyen</i>	<i>18th Essex</i>
<i>Michael S. Day</i>	<i>31st Middlesex</i>
<i>Steven Ultrino</i>	<i>33rd Middlesex</i>
<i>Danielle W. Gregoire</i>	<i>4th Middlesex</i>
<i>David M. Rogers</i>	<i>24th Middlesex</i>
<i>William L. Crocker, Jr.</i>	<i>2nd Barnstable</i>
<i>Patrick M. O'Connor</i>	<i>Plymouth and Norfolk</i>
<i>Mathew J. Muratore</i>	<i>1st Plymouth</i>

<i>Paul McMurtry</i>	<i>11th Norfolk</i>
<i>Mike Connolly</i>	<i>26th Middlesex</i>
<i>Brian M. Ashe</i>	<i>2nd Hampden</i>
<i>Carlos Gonzalez</i>	<i>10th Hampden</i>
<i>Hannah Kane</i>	<i>11th Worcester</i>
<i>Angelo L. D'Emilia</i>	<i>8th Plymouth</i>
<i>Natalie M. Higgins</i>	<i>4th Worcester</i>
<i>Denise C. Garlick</i>	<i>13th Norfolk</i>
<i>Shaunna L. O'Connell</i>	<i>3rd Bristol</i>
<i>Mary S. Keefe</i>	<i>15th Worcester</i>
<i>Joseph D. McKenna</i>	<i>18th Worcester</i>
<i>Carmine Lawrence Gentile</i>	<i>13th Middlesex</i>
<i>Alice Hanlon Peisch</i>	<i>14th Norfolk</i>
<i>Kate Hogan</i>	<i>3rd Middlesex</i>
<i>Denise Provost</i>	<i>27th Middlesex</i>
<i>Marjorie C. Decker</i>	<i>25th Middlesex</i>
<i>Daniel R. Cullinane</i>	<i>12th Suffolk</i>
<i>Ruth B. Balsler</i>	<i>12th Middlesex</i>
<i>Jon Santiago</i>	<i>9th Suffolk</i>
<i>Paul K. Frost</i>	<i>7th Worcester</i>
<i>Sean Garballey</i>	<i>23rd Middlesex</i>
<i>James Arciero</i>	<i>2nd Middlesex</i>
<i>Jack Patrick Lewis</i>	<i>7th Middlesex</i>
<i>Carolyn C. Dykema</i>	<i>8th Middlesex</i>

HOUSE No.

[Pin Slip]

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-First General Court
(2019-2020)**

An Act relative to fail first 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 111 of the General Laws is hereby amended by adding the
2 following section:-

3 Section 237. There shall be a commission on step therapy protocols within the
4 department. The commission shall consist of: the commissioner of public health or the
5 commissioner’s designee, who shall chair the commission; the commissioner of insurance or the
6 commissioner’s designee; the director of MassHealth or the director’s designee; the director of
7 the Center of Health Information and Analysis or the director’s designee; a member representing
8 the Massachusetts Public Health Association; and 3 members to be selected by the Governor
9 including: a member representing one of the top five health insurance companies in
10 Massachusetts according to market share, a member representing a patient advocacy
11 organization, and a member currently practicing as a licensed physician in Massachusetts.

12 The commission on step therapy protocol shall study and assess the implementation of
13 step therapy process reforms. The study shall address the impact of step therapy protocols on

14 total medical expenses, health care quality outcomes, and costs to the Massachusetts health care
15 system. The study shall also examine the impact of step therapy protocols on health disparities as
16 relates to outcomes, access and medication adherence in the Commonwealth.

17 The commission shall convene no later than ninety days of the effective date of this act
18 and meet as needed to meet the reporting requirements of this section.

19 The commission on step therapy protocols shall submit to the secretary of health and
20 human services and the joint committee public health, nine months after the effective date of this
21 act and annually thereafter, a report that includes findings from the commission's review along
22 with recommendations and any suggested legislation to implement those recommendations.

23 SECTION 2. Commercial Health Insurance Step Therapy Exceptions

24 (a)(1) "Clinical practice guidelines" means a systematically developed statement to assist
25 decision making by health care providers and patient decisions about appropriate healthcare for
26 specific clinical circumstances and conditions.

27 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,
28 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
29 organization to determine the medical necessity and appropriateness of healthcare services.

30 (3) "Medically necessary" mean health services and supplies that under the applicable
31 standard of care are appropriate: (a) to improve or preserve health, life, or function; (b) to slow
32 the deterioration of health, life, or function; or (c) for the early screening, prevention, evaluation,
33 diagnosis or treatment of a disease, condition, illness or injury.

34 (4) “Step therapy protocol” means a protocol, policy, or program that establishes the
35 specific sequence in which prescription drugs for a specified medical condition and medically
36 appropriate for a particular patient are covered by an insurer or health plan.

37 (5) “Step therapy exception” means that a step therapy protocol should be overridden in
38 favor of immediate coverage of the health care provider’s selected prescription drug.

39 (6) “Utilization review organization” means an entity that conducts utilization review,
40 other than a insurer or health plan performing utilization review for its own health benefit plans.

41 (b)(1) Clinical review criteria used to establish a step therapy protocol shall be based on
42 clinical practice guidelines that:

43 (A) Recommend that the prescription drugs be taken in the specific sequence required by
44 the step therapy protocol.

45 (B) Are developed and endorsed by a multidisciplinary panel of experts that manages
46 conflicts of interest among the members of the writing and review groups by:

47 (i) Requiring members to disclose any potential conflict of interests with entities,
48 including insurers, health plans, and pharmaceutical manufacturers and recuse themselves from
49 voting if they have a conflict of interest.

50 (ii) Using a methodologist to work with writing groups to provide objectivity in data
51 analysis and ranking of evidence through the preparation of evidence tables and facilitating
52 consensus.

53 (iii) Offering opportunities for public review and comments.

54 (C) Are based on high quality studies, research, and medical practice.

55 (D) Are created by an explicit and transparent process that:

56 (i) Minimizes biases and conflicts of interest;

57 (ii) Explains the relationship between treatment options and outcomes;

58 (iii) Rates the quality of the evidence supporting recommendations; and

59 (iv) Considers relevant patient subgroups and preferences.

60 (E) Are continually updated through a review of new evidence, research and newly
61 developed treatments.

62 (2) In the absence of clinical guidelines that meet the requirements in subsection (b)(1) of
63 this section, peer reviewed publications may be substituted.

64 (3) When establishing a step therapy protocol, a utilization review agent shall also take
65 into account the needs of atypical patient populations and diagnoses when establishing clinical
66 review criteria.

67 (4) This section shall not be construed to require insurers, health plans or the state to set
68 up a new entity to develop clinical review criteria used for step therapy protocols.

69 (c)(1) When coverage of a prescription drug for the treatment of any medical condition is
70 restricted for use by an insurer, health plan, or utilization review organization through the use of
71 a step therapy protocol, the patient and prescribing practitioner shall have access to a clear
72 readily accessible and convenient process to request a step therapy exception. An insurer, health
73 plan, or utilization review organization may use its existing medical exceptions process to satisfy

74 this requirement. The process shall be made easily accessible on the insurer's, health plan's, or
75 utilization review organization's website.

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

77 (A) The required prescription drug is contraindicated or will likely cause an adverse
78 reaction by or physical or mental harm to the patient;

79 (B) The required prescription drug is expected to be ineffective based on the known
80 clinical characteristics of the patient and the known characteristics of the prescription drug
81 regimen;

82 (C) The patient has tried the required prescription drug while under their current or a
83 previous health insurance or health benefit plan, or another prescription drug in the same
84 pharmacologic class or with the same mechanism of action and such prescription drug was
85 discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

86 (D) The required prescription drug is not in the best interest of the patient, based on
87 medical necessity.

88 (E) The patient is stable on a prescription drug selected by their health care provider for
89 the medical condition under consideration while on a current or previous health insurance or
90 health benefit plan.

91 (3) Upon the granting of a step therapy exception, the insurer, health plan, or utilization
92 review organization shall authorize coverage for the prescription drug prescribed by the patient's
93 treating health care provider.

94 (4) The insurer, health plan, or utilization review organization shall grant or deny a step
95 therapy exception request or an appeal within seventy-two hours of receipt. In cases where
96 exigent circumstances exist an insurer, health plan, or utilization review organization shall
97 respond within twenty-four hours of receipts. Should a response by an insurer, health plan, or
98 utilization review organization not be received within the time allotted, the exception or appeal
99 shall be deemed granted.

100 (5) This section shall apply to [LIST ALL STATE REGULATED COMMERCIAL
101 PLAN TYPES] that provide coverage of a prescription drug pursuant to a policy that meets the
102 definition of a medication step therapy protocol as defined in this Act, regardless of whether the
103 policy is described as a step therapy protocol.

104 (d) Any step therapy exception as defined in this Act shall be eligible for appeal by an
105 insured.

106 (e) Notwithstanding any law to the contrary, the [Division of Insurance] shall promulgate
107 any regulations necessary to enforce this section.

108 (f) This Act shall apply only to a health insurance and/or health benefit plans delivered,
109 issued for delivery, or renewed on or after January 1, 2020.

110 SECTION 3. Medicaid Program Step Therapy Exceptions

111 (a) “Medically necessary,” “step therapy protocol,” “step therapy exception,” and
112 “utilization review organization” shall have the same meaning in this section as in Section 1.

113 (b)(1) On or after January 1, 2020, when coverage of a prescription drug for the treatment
114 of any medical condition is restricted for use by MassHealth, or by a managed care organization

115 or utilization review organization contracted with MassHealth to provide coverage to Medicaid
116 recipients, through the use of a step therapy protocol, a request for exception from such
117 requirements shall be expeditiously granted if:

118 (A) The required prescription drug is contraindicated or will likely cause an adverse
119 reaction by or physical or mental harm to the patient;

120 (B) The required prescription drug is expected to be ineffective based on the known
121 clinical characteristics of the patient and the known characteristics of the prescription drug
122 regimen;

123 (C) The patient has tried the required prescription drug while covered under MassHealth,
124 a managed care organization or utilization review organization contracted with MassHealth or a
125 previous health insurance or health benefit plan, or another prescription drug in the same
126 pharmacologic class or with the same mechanism of action and such prescription drug was
127 discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

128 (D) The required prescription drug is not in the best interest of the patient, based on
129 medical necessity.

130 (E) The patient is stable on a prescription drug selected by their health care provider for
131 the medical condition under consideration while covered under MassHealth, a managed care
132 organization or utilization review organization contracted with MassHealth or previous health
133 insurance or health benefit plan.

134 (2) Upon the granting of a step therapy exception, MassHealth or a managed care
135 organization or utilization review organization contracted with MassHealth shall authorize
136 coverage for the prescription drug prescribed by the patient's treating health care provider.

137 (3) The MassHealth or a managed care organization or utilization review organization
138 contracted with MassHealth review process for step therapy exception requests shall meet the
139 requirements set forth in 1972(d)(5)(A) of the federal Social Security Act.

140 Section 3. Limitations

141 (a) Nothing in this Act shall not be construed to prevent:

142 (1) A pharmacist from effecting substitutions of prescription drugs consistent with [insert
143 state pharmacy substitution law reference(s)].

144 (2) A health care provider from prescribing a prescription drug that is determined to be
145 medically appropriate.