

**SENATE . . . . . No.**

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**The Commonwealth of Massachusetts**

PRESENTED BY:

*Julian Cyr*

*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:

*Julian Cyr*

DISTRICT/ADDRESS:

*Cape and Islands*

**SENATE . . . . . No.**

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[Pin Slip]

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**The Commonwealth of Massachusetts**

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

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

11           The commission on step therapy protocol shall study and assess the implementation of  
12 step therapy process reforms. The study shall address the impact of step therapy protocols on  
13 total medical expenses, health care quality outcomes, and costs to the Massachusetts health care

14 system. The study shall also examine the impact of step therapy protocols on health disparities  
15 as relates to outcomes, access and medication adherence in the Commonwealth.

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

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

#### 22 Section 237A. Commercial Health Insurance Step Therapy Exceptions

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

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

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

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

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

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

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

42 (i) recommend that the prescription drugs be taken in the specific sequence required by  
43 the step therapy protocol;

44 (ii) are developed and endorsed by a multidisciplinary panel of experts that manages  
45 conflicts of interest among the members of the writing and review groups by: (A) requiring  
46 members to disclose any potential conflict of interests with entities, including insurers, health  
47 plans, and pharmaceutical manufacturers and recuse themselves from voting if they have a  
48 conflict of interest, (B) using a methodologist to work with writing groups to provide objectivity  
49 in data analysis and ranking of evidence through the preparation of evidence tables and  
50 facilitating consensus, and (C) offering opportunities for public review and comments;

51 (iii) are based on high quality studies, research, and medical practice;

52 (iv) are created by an explicit and transparent process that: (A) minimizes biases and  
53 conflicts of interest, (B) explains the relationship between treatment options and outcomes, (C)

54 rates the quality of the evidence supporting recommendations, and (D) considers relevant patient  
55 subgroups and preferences; and

56 (v) are continually updated through a review of new evidence, research and newly  
57 developed treatments.

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

60 When establishing a step therapy protocol, a utilization review agent shall also take into  
61 account the needs of atypical patient populations and diagnoses when establishing clinical review  
62 criteria.

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

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

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

73 (i) the required prescription drug is contraindicated or will likely cause an adverse  
74 reaction by or physical or mental harm to the patient;

75 (ii) the required prescription drug is expected to be ineffective based on the known  
76 clinical characteristics of the patient and the known characteristics of the prescription drug  
77 regimen;

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

82 (iv) the required prescription drug is not in the best interest of the patient, based on  
83 medical necessity; and

84 (v) the patient is stable on a prescription drug selected by their health care provider for  
85 the medical condition under consideration while on a current or previous health insurance or  
86 health benefit plan.

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

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

96 (5) This section shall apply to all commercial plans in the commonwealth that provide  
97 coverage of a prescription drug pursuant to a policy that meets the definition of a medication step  
98 therapy protocol as defined in this Act, regardless of whether the policy is described as a step  
99 therapy protocol.

100 (d) Any step therapy exception as defined in this section shall be eligible for appeal by  
101 an insured.

102 (e) Notwithstanding any law to the contrary, the division of insurance shall promulgate  
103 any regulations necessary to enforce this section.

104 (f) This section shall apply only to a health insurance or health benefit plans delivered,  
105 issued for delivery, or renewed on or after January 1, 2020.

106 Section 237B. Medicaid Program Step Therapy Exceptions

107 (a) “Medically necessary”, “step therapy protocol”, “step therapy exception”, and  
108 “utilization review organization” shall have the same meaning in this section as in Section 237A.

109 (b)(1) On or after January 1, 2020, when coverage of a prescription drug for the treatment  
110 of any medical condition is restricted for use by MassHealth, or by a managed care organization  
111 or utilization review organization contracted with MassHealth to provide coverage to Medicaid  
112 recipients, through the use of a step therapy protocol, a request for exception from such  
113 requirements shall be expeditiously granted if:

114 (i) the required prescription drug is contraindicated or will likely cause an adverse  
115 reaction by or physical or mental harm to the patient;

116 (ii) the required prescription drug is expected to be ineffective based on the known  
117 clinical characteristics of the patient and the known characteristics of the prescription drug  
118 regimen;

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

124 (iv) the required prescription drug is not in the best interest of the patient, based on  
125 medical necessity; or

126 (v) the patient is stable on a prescription drug selected by their health care provider for  
127 the medical condition under consideration while covered under MassHealth, a managed care  
128 organization or utilization review organization contracted with MassHealth or previous health  
129 insurance or health benefit plan.

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

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

136 Section 237C. Limitations



137 (a) Nothing in section 237, section 237A or section 237B shall be construed to prevent:  
138 (1) a pharmacist from effecting substitutions of prescription drugs consistent with section 12D of  
139 chapter 112; or (2) a health care provider from prescribing a prescription drug that is determined  
140 to be medically appropriate.