

**HOUSE . . . . . No. 791**

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**The Commonwealth of Massachusetts**

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PRESENTED BY:

*Jennifer E. Benson*

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*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 patient medication adherence.

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PETITION OF:

NAME:	DISTRICT/ADDRESS:
<i>Jennifer E. Benson</i>	<i>37th Middlesex</i>
<i>Jeffrey N. Roy</i>	<i>10th Norfolk</i>
<i>Paul McMurtry</i>	<i>11th Norfolk</i>

**HOUSE . . . . . No. 791**

By Ms. Benson of Lunenburg, a petition (accompanied by bill, House, No. 791) of Jennifer E. Benson, Jeffrey N. Roy and Paul McMurtry relative to certain requirements and restrictions for prescription drug coverage and step-therapy protocols. Financial Services.

**The Commonwealth of Massachusetts**

**In the One Hundred and Eighty-Ninth General Court  
(2015-2016)**

An Act relative to patient medication adherence.

*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 175 of the General Laws is hereby amended by inserting after  
2 section 47BB the following section:-

3 Section 47CC. (a) As used in this section the following words shall, unless the context  
4 clearly requires otherwise, have the following meanings:-

5 “Clinical practice guidelines” means a systematically developed statement to assist  
6 practitioner and patient decisions about appropriate healthcare for specific clinical  
7 circumstances.

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

11 “Step Therapy Protocol” means a protocol or program that establishes the specific  
12 sequence in which prescription drugs for a specified medical condition and medically appropriate  
13 for a particular patient are to be prescribed and paid for by a health plan.

14 “Step Therapy Override Determination” means a determination as to whether step  
15 therapy should apply in a particular situation, or whether the step therapy protocol should be  
16 overridden in favor of immediate coverage of the patient’s and/or prescriber’s preferred drug.  
17 This determination is based on a review of the patient’s and/or prescriber’s request for an  
18 override, along with supporting rationale and documentation.

19 “Utilization review organization” means an entity that conducts utilization review, other  
20 than a health carrier performing utilization review for its own health benefit plans.

21 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or  
22 renewed within the commonwealth that provides coverage for prescription drugs and uses step-  
23 therapy protocols shall have the following requirements and restrictions.

24 (1) Clinical review criteria used to establish step therapy protocols shall be based on  
25 clinical practice guidelines:

26 (A) Independently developed by a professional medical society with expertise in the  
27 medical condition, or conditions, for which coverage decisions said criteria will be applied; and

28 (B) That recommend drugs be taken in the specific sequence required by the step  
29 therapy protocol.

30 (2) Exceptions Process. When coverage of medications for the treatment of any  
31 medical condition are restricted for use by an insurer, health plan, or utilization review

32 organization via a step therapy protocol, the patient and prescribing practitioner shall have access  
33 to a clear and convenient process to request a Step Therapy Exception Determination. An  
34 insurer, health plan, or utilization review organization may use its existing medical exceptions  
35 process to satisfy this requirement. The process shall be disclosed to the patient and health care  
36 providers, including documenting and making easily accessible on the insurer's or health plan's  
37 website.

38 (3) Exceptions. An exception request shall be expeditiously granted if:

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

41 (B) The required drug is expected to be ineffective based on the known relevant  
42 physical or mental characteristics of the insured and the known characteristics of the drug  
43 regimen;

44 (C) The enrollee has tried the step therapy-required drug while under their current or a  
45 previous health plan, or another drug in the same pharmacologic class or with the same  
46 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,  
47 diminished effect, or an adverse event;

48 (D) The patient is stable on a drug recommended by their health care provider for the  
49 medical condition under consideration, based on, but not limited to, a trial with medication  
50 samples or a prescription filled at a pharmacy;

51 (E) The step therapy-required drug is not in the best interest of the patient, based on  
52 medical appropriateness.

53 (4) Effect of Exception. Upon the granting of an exception request, the insurer, health  
54 plan, utilization review organization, or other entity shall authorize dispensation of and coverage  
55 for the drug prescribed by the enrollee’s treating health care provider, provided such drug is a  
56 covered drug under such policy or contract.

57 (5) Limitations. This section shall not be construed to prevent:

58 (A) An insurer, health plan, or utilization review organization from requiring an  
59 enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent  
60 branded drug;

61 (B) A health care provider from prescribing a drug he or she determines is medically  
62 appropriate.

63 SECTION 2. Chapter 176A of the General Laws is hereby amended by inserting after  
64 section 8EE the following section:-

65 Section 8FF. (a) As used in this section the following words shall, unless the context  
66 clearly requires otherwise, have the following meanings:-

67 “Clinical practice guidelines” means a systematically developed statement to assist  
68 practitioner and patient decisions about appropriate healthcare for specific clinical  
69 circumstances.

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

73 “Step Therapy Protocol” means a protocol or program that establishes the specific  
74 sequence in which prescription drugs for a specified medical condition and medically appropriate  
75 for a particular patient are to be prescribed and paid for by a health plan.

76 “Step Therapy Override Determination” means a determination as to whether step  
77 therapy should apply in a particular situation, or whether the step therapy protocol should be  
78 overridden in favor of immediate coverage of the patient’s and/or prescriber’s preferred drug.  
79 This determination is based on a review of the patient’s and/or prescriber’s request for an  
80 override, along with supporting rationale and documentation.

81 “Utilization review organization” means an entity that conducts utilization review, other  
82 than a health carrier performing utilization review for its own health benefit plans.

83 (b) Any contract between a subscriber and the corporation under an individual or group  
84 hospital service plan which is delivered, issued or renewed within the commonwealth that  
85 provides coverage for prescription drugs and uses step-therapy protocols shall have the following  
86 requirements and restrictions.

87 (1) Clinical review criteria used to establish step therapy protocols shall be based on  
88 clinical practice guidelines:

89 (A) Independently developed by a professional medical society with expertise in the  
90 medical condition, or conditions, for which coverage decisions said criteria will be applied; and

91 (B) That recommend drugs be taken in the specific sequence required by the step  
92 therapy protocol.

93           (2)    Exceptions Process. When coverage of medications for the treatment of any  
94 medical condition are restricted for use by an insurer, health plan, or utilization review  
95 organization via a step therapy protocol, the patient and prescribing practitioner shall have access  
96 to a clear and convenient process to request a Step Therapy Exception Determination. An  
97 insurer, health plan, or utilization review organization may use its existing medical exceptions  
98 process to satisfy this requirement. The process shall be disclosed to the patient and health care  
99 providers, including documenting and making easily accessible on the insurer's or health plan's  
100 website.

101           (3)    Exceptions. An exception request shall be expeditiously granted if:

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

104           (B)    The required drug is expected to be ineffective based on the known relevant  
105 physical or mental characteristics of the insured and the known characteristics of the drug  
106 regimen;

107           (C)    The enrollee has tried the step therapy-required drug while under their current or a  
108 previous health plan, or another drug in the same pharmacologic class or with the same  
109 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,  
110 diminished effect, or an adverse event;

111           (D)    The patient is stable on a drug recommended by their health care provider for the  
112 medical condition under consideration, based on, but not limited to, a trial with medication  
113 samples or a prescription filled at a pharmacy;

114 (E) The step therapy-required drug is not in the best interest of the patient, based on  
115 medical appropriateness.

116 (4) Effect of Exception. Upon the granting of an exception request, the insurer, health  
117 plan, utilization review organization, or other entity shall authorize dispensation of and coverage  
118 for the drug prescribed by the enrollee's treating health care provider, provided such drug is a  
119 covered drug under such policy or contract.

120 (5) Limitations. This section shall not be construed to prevent:

121 (A) An insurer, health plan, or utilization review organization from requiring an  
122 enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent  
123 branded drug;

124 (B) A health care provider from prescribing a drug he or she determines is medically  
125 appropriate.

126 SECTION 3. Chapter 176B of the General Laws is hereby amended by inserting after  
127 section 4EE the following section:-

128 Section 4FF. (a) As used in this section the following words shall, unless the context  
129 clearly requires otherwise, have the following meanings:-

130 "Clinical practice guidelines" means a systematically developed statement to assist  
131 practitioner and patient decisions about appropriate healthcare for specific clinical  
132 circumstances.

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

136           “Step Therapy Protocol” means a protocol or program that establishes the specific  
137 sequence in which prescription drugs for a specified medical condition and medically appropriate  
138 for a particular patient are to be prescribed and paid for by a health plan.

139           “Step Therapy Override Determination” means a determination as to whether step  
140 therapy should apply in a particular situation, or whether the step therapy protocol should be  
141 overridden in favor of immediate coverage of the patient’s and/or prescriber’s preferred drug.  
142 This determination is based on a review of the patient’s and/or prescriber’s request for an  
143 override, along with supporting rationale and documentation.

144           “Utilization review organization” means an entity that conducts utilization review, other  
145 than a health carrier performing utilization review for its own health benefit plans.

146           (b) Any subscription certificate under an individual or group medical service agreement  
147 delivered, issued or renewed within the commonwealth that provides coverage for prescription  
148 drugs and uses step-therapy protocols shall have the following requirements and restrictions.

149           (1)    Clinical review criteria used to establish step therapy protocols shall be based on  
150 clinical practice guidelines:

151           (A)    Independently developed by a professional medical society with expertise in the  
152 medical condition, or conditions, for which coverage decisions said criteria will be applied; and

153 (B) That recommend drugs be taken in the specific sequence required by the step  
154 therapy protocol.

155 (2) Exceptions Process. When coverage of medications for the treatment of any  
156 medical condition are restricted for use by an insurer, health plan, or utilization review  
157 organization via a step therapy protocol, the patient and prescribing practitioner shall have access  
158 to a clear and convenient process to request a Step Therapy Exception Determination. An  
159 insurer, health plan, or utilization review organization may use its existing medical exceptions  
160 process to satisfy this requirement. The process shall be disclosed to the patient and health care  
161 providers, including documenting and making easily accessible on the insurer's or health plan's  
162 website.

163 (3) Exceptions. An exception request shall be expeditiously granted if:

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

166 (B) The required drug is expected to be ineffective based on the known relevant  
167 physical or mental characteristics of the insured and the known characteristics of the drug  
168 regimen;

169 (C) The enrollee has tried the step therapy-required drug while under their current or a  
170 previous health plan, or another drug in the same pharmacologic class or with the same  
171 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,  
172 diminished effect, or an adverse event;

173 (D) The patient is stable on a drug recommended by their health care provider for the  
174 medical condition under consideration, based on, but not limited to, a trial with medication  
175 samples or a prescription filled at a pharmacy;

176 (E) The step therapy-required drug is not in the best interest of the patient, based on  
177 medical appropriateness.

178 (4) Effect of Exception. Upon the granting of an exception request, the insurer, health  
179 plan, utilization review organization, or other entity shall authorize dispensation of and coverage  
180 for the drug prescribed by the enrollee's treating health care provider, provided such drug is a  
181 covered drug under such policy or contract.

182 (5) Limitations. This section shall not be construed to prevent:

183 (A) An insurer, health plan, or utilization review organization from requiring an  
184 enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent  
185 branded drug;

186 (B) A health care provider from prescribing a drug he or she determines is medically  
187 appropriate.

188 SECTION 4. Chapter 176G of the General Laws is hereby amended by inserting after  
189 section 4W the following section:-

190 Section 4X. (a) As used in this section the following words shall, unless the context  
191 clearly requires otherwise, have the following meanings:

192 “Clinical practice guidelines” means a systematically developed statement to assist  
193 practitioner and patient decisions about appropriate healthcare for specific clinical  
194 circumstances.

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

198 “Step Therapy Protocol” means a protocol or program that establishes the specific  
199 sequence in which prescription drugs for a specified medical condition and medically appropriate  
200 for a particular patient are to be prescribed and paid for by a health plan.

201 “Step Therapy Override Determination” means a determination as to whether step  
202 therapy should apply in a particular situation, or whether the step therapy protocol should be  
203 overridden in favor of immediate coverage of the patient’s and/or prescriber’s preferred drug.  
204 This determination is based on a review of the patient’s and/or prescriber’s request for an  
205 override, along with supporting rationale and documentation.

206 “Utilization review organization” means an entity that conducts utilization review, other  
207 than a health carrier performing utilization review for its own health benefit plans.

208 (b) Any individual or group health maintenance that provides coverage for prescription  
209 drugs and uses step-therapy protocols shall have the following requirements and restrictions.

210 (1) Clinical review criteria used to establish step therapy protocols shall be based on  
211 clinical practice guidelines:

212 (A) Independently developed by a professional medical society with expertise in the  
213 medical condition, or conditions, for which coverage decisions said criteria will be applied; and

214 (B) That recommend drugs be taken in the specific sequence required by the step  
215 therapy protocol.

216 (2) Exceptions Process. When coverage of medications for the treatment of any  
217 medical condition are restricted for use by an insurer, health plan, or utilization review  
218 organization via a step therapy protocol, the patient and prescribing practitioner shall have access  
219 to a clear and convenient process to request a Step Therapy Exception Determination. An  
220 insurer, health plan, or utilization review organization may use its existing medical exceptions  
221 process to satisfy this requirement. The process shall be disclosed to the patient and health care  
222 providers, including documenting and making easily accessible on the insurer's or health plan's  
223 website.

224 (3) Exceptions. An exception request shall be expeditiously granted if:

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

227 (B) The required drug is expected to be ineffective based on the known relevant  
228 physical or mental characteristics of the insured and the known characteristics of the drug  
229 regimen;

230 (C) The enrollee has tried the step therapy-required drug while under their current or a  
231 previous health plan, or another drug in the same pharmacologic class or with the same

232 mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,  
233 diminished effect, or an adverse event;

234 (D) The patient is stable on a drug recommended by their health care provider for the  
235 medical condition under consideration, based on, but not limited to, a trial with medication  
236 samples or a prescription filled at a pharmacy;

237 (E) The step therapy-required drug is not in the best interest of the patient, based on  
238 medical appropriateness.

239 (4) Effect of Exception. Upon the granting of an exception request, the insurer, health  
240 plan, utilization review organization, or other entity shall authorize dispensation of and coverage  
241 for the drug prescribed by the enrollee's treating health care provider, provided such drug is a  
242 covered drug under such policy or contract.

243 (5) Limitations. This section shall not be construed to prevent:

244 (A) An insurer, health plan, or utilization review organization from requiring an  
245 enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent  
246 branded drug;

247 (B) A health care provider from prescribing a drug he or she determines is medically  
248 appropriate.

249 SECTION 5. Sections 1 to 5, inclusive, shall apply to all policies, contracts and  
250 certificates of health insurance subject to section 17K of chapter 32A, section 47CC of chapter  
251 175, section 8FF of chapter 176A, section 4FF of chapter 176B and section 4X of chapter 176G  
252 of the General Laws which are delivered, issued or renewed on or after January 1, 2016.