

HOUSE No. 791

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 patient medication adherence.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Jennifer E. Benson</i>	<i>37th Middlesex</i>	<i>1/15/2015</i>
<i>Jeffrey N. Roy</i>	<i>10th Norfolk</i>	<i>9/4/2019</i>
<i>Paul McMurtry</i>	<i>11th Norfolk</i>	<i>9/4/2019</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.