

SENATE No. 2486

Senate, May 24, 2016 – Text of amendment (522) (offered by Senator L'Italien) to the Ways and Means amendment (Senate, No. 4) to the House Bill making appropriations for the fiscal year 2017 for the maintenance of the departments, boards, commissions, institutions and certain activities of the Commonwealth, for interest, sinking fund and serial bond requirements and for certain permanent improvements.

The Commonwealth of Massachusetts

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

1 by inserting the following new sections:-

2 SECTION X. Chapter 175 of the General Laws is hereby amended by inserting after
3 section 47BB the following section:-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

52 (4) Effect of Exception. Upon the granting of an exception request, the insurer, health
53 plan, utilization review organization, or other entity shall authorize dispensation of and coverage

54 for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
55 covered drug under such policy or contract.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

92 (2) Exceptions Process. When coverage of medications for the treatment of any medical
93 condition are restricted for use by an insurer, health plan, or utilization review organization via a
94 step therapy protocol, the patient and prescribing practitioner shall have access to a clear and
95 convenient process to request a Step Therapy Exception Determination. An insurer, health plan,

96 or utilization review organization may use its existing medical exceptions process to satisfy this
97 requirement. The process shall be disclosed to the patient and health care providers, including
98 documenting and making easily accessible on the insurer's or health plan's website.

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

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

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

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

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

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

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

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

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

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

123 SECTION XX. Chapter 176B of the General Laws is hereby amended by inserting after
124 section 4EE the following section:-

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

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

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

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

136 “Step Therapy Override Determination” means a determination as to whether step
137 therapy should apply in a particular situation, or whether the step therapy protocol should be

138 overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug.
139 This determination is based on a review of the patient's and/or prescriber's request for an
140 override, along with supporting rationale and documentation.

141 "Utilization review organization" means an entity that conducts utilization review, other
142 than a health carrier performing utilization review for its own health benefit plans.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

196 “Step Therapy Override Determination” means a determination as to whether step
197 therapy should apply in a particular situation, or whether the step therapy protocol should be
198 overridden in favor of immediate coverage of the patient’s and/or prescriber’s preferred drug.

199 This determination is based on a review of the patient’s and/or prescriber’s request for an
200 override, along with supporting rationale and documentation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

242 SECTION XX. Sections 1 to 5, inclusive, shall apply to all policies, contracts and
243 certificates of health insurance subject to section 17K of chapter 32A, section 47CC of chapter
244 175, section 8FF of chapter 176A, section 4FF of chapter 176B and section 4X of chapter 176G
245 of the General Laws which are delivered, issued or renewed on or after January 1, 2016.