

# SENATE . . . . . No. 2120

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Senate, May 24, 2017 -- Text of amendment (519) (offered by Senator L'Italien) to the Ways and Means amendment (Senate, No. 3) to the House Bill making appropriations for the fiscal year 2018 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

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## The Commonwealth of Massachusetts

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In the One Hundred and Ninetieth General Court  
(2017-2018)  
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1 SECTION X. Chapter 175 of the General Laws, as appearing in the 2016 Official  
2 Edition, is hereby amended by inserting after section 47BB the following new 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 circumstances  
7 and conditions.

8 "Clinical review criteria" means the written screening procedures, decision abstracts,  
9 clinical protocols and practice guidelines used by a carrier or utilization review organization to  
10 determine the 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 and are covered as a pharmacy or medical benefit by a carrier, including  
14 self-administered and physician-administered drugs.

15 “Step Therapy Override Exception Determination” means a determination as to whether  
16 step 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 that:

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

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

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

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

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

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

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

40 (i) Minimizes biases and conflicts of interest;

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

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

43 (iv) Considers relevant patient subgroups and preferences.

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

46 (2) In the absence of clinical guidelines that meet the requirements in section (1), peer  
47 reviewed publications may be substituted.

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

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

53 (c) When coverage of medications for the treatment of any medical condition are  
54 restricted for use by a carrier or utilization review organization via a step therapy protocol, the  
55 patient and prescribing practitioner shall have access to a clear readily accessible and convenient  
56 process to request a Step Therapy Exception Determination. A carrier or utilization review  
57 organization may use its existing medical exceptions process to satisfy this requirement. The  
58 process shall be disclosed to the patient and health care providers, including documenting and  
59 making easily accessible on the carriers' or utilization review organization's website.

60 (d) A step therapy override exception determination shall be expeditiously granted if:

61 (1) The required drug is contraindicated or will likely cause an adverse reaction by or  
62 physical or mental harm to the patient;

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

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

69 (4) The patient is stable on a drug recommended by their health care provider for the  
70 medical condition under consideration while on a current or previous health insurance or health  
71 benefit plan;

72 (5) The step therapy-required drug is not in the best interest of the patient, based on  
73 medical appropriateness.

74 (e) Upon the granting of a step therapy override exception determination, the carrier or  
75 utilization review organization shall authorize coverage for the drug prescribed by the enrollee's  
76 treating health care provider.

77 (f) The carrier or utilization review organization shall respond to step therapy override  
78 exception request or an appeal within seventy two hours of receipt. In cases where exigent  
79 circumstances exist a carrier or utilization review organization shall respond within twenty four  
80 hours of receipts. Should a response by a carrier or utilization review organization not be  
81 received within this time allotted the exception or appeal shall be deemed granted.

82 (g) This section shall not be construed to prevent:

83 (1) A carrier or utilization review organization from requiring an enrollee try an AB-  
84 rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

85 (2) A health care provider from prescribing a drug he or she determines is medically  
86 appropriate.

87

88 SECTION XX. Chapter 176A of the General Laws, as Appearing in the 2016 Official  
89 Edition, is hereby amended by inserting after section 8EE the following new section:-

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

92 "Clinical practice guidelines" means a systematically developed statement to assist  
93 practitioner and patient decisions about appropriate healthcare for specific clinical circumstances  
94 and conditions.

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

98 “Step therapy protocol” means a protocol or program that establishes the specific  
99 sequence in which prescription drugs for a specified medical condition and medically appropriate  
100 for a particular patient and are covered as a pharmacy or medical benefit by a carrier, including  
101 self-administered and physician-administered drugs, .

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

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

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

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

115 (A) That recommend drugs be taken in the specific sequence required by the step therapy  
116 protocol.

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

119 (i) Requiring members to disclose any potential conflict of interests with entities,  
120 including insurers, health plans, and pharmaceutical manufacturers and reclude themselves of  
121 voting if they have a conflict of interest.

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

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

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

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

128 (i) Minimizes biases and conflicts of interest;

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

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

131 (iv) Considers relevant patient subgroups and preferences.

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

134 (2) In the absence of clinical guidelines that meet the requirements in section (1), peer  
135 reviewed publications may be substituted.

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

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

141 (c) When coverage of medications for the treatment of any medical condition are  
142 restricted for use by a carrier or utilization review organization via a step therapy protocol, the  
143 patient and prescribing practitioner shall have access to a clear readily accessible and convenient  
144 process to request a Step Therapy Exception Determination. A carrier or utilization review  
145 organization may use its existing medical exceptions process to satisfy this requirement. The  
146 process shall be disclosed to the patient and health care providers, including documenting and  
147 making easily accessible on the carriers' or utilization review organization's website.

148 (d) A step therapy override exception determination shall be expeditiously granted if:

149 (1) The required drug is contraindicated or will likely cause an adverse reaction by or  
150 physical or mental harm to the patient;

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

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



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

157 (4) The patient is stable on a drug recommended by their health care provider for the  
158 medical condition under consideration while on a current or previous health insurance or health  
159 benefit plan;

160 (5) The step therapy-required drug is not in the best interest of the patient, based on  
161 medical appropriateness.

162 (e) Upon the granting of a step therapy override exception determination, the carrier or  
163 utilization review organization shall authorize coverage for the drug prescribed by the enrollee's  
164 treating health care provider.

165 (f) The carrier or utilization review organization shall respond to step therapy override  
166 exception request or an appeal within seventy two hours of receipt. In cases where exigent  
167 circumstances exist a carrier or utilization review organization shall respond within twenty four  
168 hours of receipts. Should a response by a carrier or utilization review organization not be  
169 received within this time allotted the exception or appeal shall be deemed granted.

170 (g) This section shall not be construed to prevent:

171 (1) A carrier or utilization review organization from requiring an enrollee try an AB-  
172 rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

173 (2) A health care provider from prescribing a drug he or she determines is medically  
174 appropriate.

175

176 SECTION XXX. Chapter 176B of the General Laws, as appearing in the 2016 Official  
177 Edition, is hereby amended by inserting after section 4EE the following new section:-

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

180 “Clinical practice guidelines” means a systematically developed statement to assist  
181 practitioner and patient decisions about appropriate healthcare for specific clinical circumstances  
182 and conditions.

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

186 “Step therapy protocol” means a protocol or program that establishes the specific  
187 sequence in which prescription drugs for a specified medical condition and medically appropriate  
188 for a particular patient and are covered under a health benefit plan as a pharmacy or medical  
189 benefit by a carrier, including self-administered and physician-administered drugs.

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

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

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

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

202 (A) That recommend drugs be taken in the specific sequence required by the step therapy  
203 protocol.

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

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

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

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

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

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

215 (i) Minimizes biases and conflicts of interest;

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

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

218 (iv) Considers relevant patient subgroups and preferences.

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

221 (2) In the absence of clinical guidelines that meet the requirements in section (1), peer  
222 reviewed publications may be substituted.

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

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

228 (c) When coverage of medications for the treatment of any medical condition are  
229 restricted for use by a carrier or utilization review organization via a step therapy protocol, the  
230 patient and prescribing practitioner shall have access to a clear readily accessible and convenient  
231 process to request a Step Therapy Exception Determination. A carrier or utilization review  
232 organization may use its existing medical exceptions process to satisfy this requirement. The  
233 process shall be disclosed to the patient and health care providers, including documenting and  
234 making easily accessible on the carriers' or utilization review organization's website.

235 (d) A step therapy override exception determination shall be expeditiously granted if:

236 (1) The required drug is contraindicated or will likely cause an adverse reaction by or  
237 physical or mental harm to the patient;

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

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

244 (4) The patient is stable on a drug recommended by their health care provider for the  
245 medical condition under consideration while on a current or previous health insurance or health  
246 benefit plan;

247 (5) The step therapy-required drug is not in the best interest of the patient, based on  
248 medical appropriateness.

249 (e) Upon the granting of a step therapy override exception determination, the carrier or  
250 utilization review organization shall authorize coverage for the drug prescribed by the enrollee's  
251 treating health care provider.

252 (f) The carrier or utilization review organization shall respond to step therapy override  
253 exception request or an appeal within seventy two hours of receipt. In cases where exigent  
254 circumstances exist a carrier or utilization review organization shall respond within twenty four  
255 hours of receipts. Should a response by a carrier or utilization review organization not be  
256 received within this time allotted the exception or appeal shall be deemed granted.

257 (g) This section shall not be construed to prevent:

258 (1) A carrier or utilization review organization from requiring an enrollee try an AB-  
259 rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

260 (2) A health care provider from prescribing a drug he or she determines is medically  
261 appropriate.

262

263 SECTION XXXX. Chapter 176G of the General Laws, as appearing in the 2016 Official  
264 Edition, is hereby amended by inserting after section 4W the following new section:-

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

267 “Clinical practice guidelines” means a systematically developed statement to assist  
268 practitioner and patient decisions about appropriate healthcare for specific clinical circumstances  
269 and conditions.

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

273 “Step therapy protocol” means a protocol or program that establishes the specific  
274 sequence in which prescription drugs for a specified medical condition and medically appropriate  
275 for a particular patient and are covered under a health benefit plan as a pharmacy or medical  
276 benefit by a carrier, including self-administered and physician-administered drugs, .

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

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

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

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

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

288 (A) That recommend drugs be taken in the specific sequence required by the step therapy  
289 protocol.

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

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

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

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

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

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

301 (i) Minimizes biases and conflicts of interest;

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

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

304 (iv) Considers relevant patient subgroups and preferences.

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

307 (2) In the absence of clinical guidelines that meet the requirements in section (1), peer  
308 reviewed publications may be substituted.

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

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

314 (c) When coverage of medications for the treatment of any medical condition are  
315 restricted for use by a carrier or utilization review organization via a step therapy protocol, the  
316 patient and prescribing practitioner shall have access to a clear readily accessible and convenient  
317 process to request a Step Therapy Exception Determination. A carrier or utilization review  
318 organization may use its existing medical exceptions process to satisfy this requirement. The



319 process shall be disclosed to the patient and health care providers, including documenting and  
320 making easily accessible on the carriers' or utilization review organization's website.

321 (d) A step therapy override exception determination shall be expeditiously granted if:

322 (1) The required drug is contraindicated or will likely cause an adverse reaction by or  
323 physical or mental harm to the patient;

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

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

330 (4) The patient is stable on a drug recommended by their health care provider for the  
331 medical condition under consideration while on a current or previous health insurance or health  
332 benefit plan;

333 (5) The step therapy-required drug is not in the best interest of the patient, based on  
334 medical appropriateness.

335 (e) Upon the granting of a step therapy override exception determination, the carrier or  
336 utilization review organization shall authorize coverage for the drug prescribed by the enrollee's  
337 treating health care provider.

338 (f) The carrier or utilization review organization shall respond to step therapy override  
339 exception request or an appeal within seventy two hours of receipt. In cases where exigent

340 circumstances exist a carrier or utilization review organization shall respond within twenty four  
341 hours of receipts. Should a response by a carrier or utilization review organization not be  
342 received within this time allotted the exception or appeal shall be deemed granted.

343 (g) This section shall not be construed to prevent:

344 (1) A carrier or utilization review organization from requiring an enrollee try an AB-  
345 rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

346 (2) A health care provider from prescribing a drug he or she determines is medically  
347 appropriate.

348

349 SECTION XXXXX. Sections 1 to 5, inclusive, shall apply to all policies, contracts and  
350 certificates of health insurance subject to section 17K of chapter 32A, section 47CC of chapter  
351 175, section 8FF of chapter 176A, section 4FF of chapter 176B and section 4X of chapter 176G  
352 of the General Laws which are delivered, issued or renewed on or after January 1, 20XX.”