

SENATE No. 2119

Senate, May 24, 2017 -- Text of amendment (334) (offered by Senator Flanagan) 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

The Commonwealth of Massachusetts

In the One Hundred and Ninetieth General Court
(2017-2018)

1 By inserting, after section __, the following new sections:-

2 “SECTION _____. Chapter 175 of the General Laws is hereby amended by inserting after
3 section 47BB the following section:-Section 47CC. (a) As used in this section the following
4 words shall, unless the context clearly requires otherwise, have the following meanings:-

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

7 conditions.“Clinical review criteria” means the written screening procedures, decision abstracts,
8 clinical protocols and practice guidelines used by a carrier or utilization review organization to

9 determine the medical necessity and appropriateness of healthcare services.“Step therapy
10 protocol” means a protocol or program that establishes the specific sequence in which

11 prescription drugs for a specified medical condition and medically appropriate for a particular
12 patient and are covered as a pharmacy or medical benefit by a carrier, including self-

13 administered and physician-administered drugs.“Step Therapy Override Exception

14 Determination” means a determination as to whether step therapy should apply in a particular

15 situation, or whether the step therapy protocol should be overridden in favor of immediate
16 coverage of the patient’s and/or prescriber’s preferred drug. This determination is based on a
17 review of the patient’s and/or prescriber’s request for an override, along with supporting
18 rationale and documentation. “Utilization review organization” means an entity that conducts
19 utilization review, other than a health carrier performing utilization review for its own health
20 benefit plans. (b) Any policy, contract, agreement, plan or certificate of insurance issued,
21 delivered or renewed within the commonwealth that provides coverage for prescription drugs
22 and uses step-therapy protocols shall have the following requirements and restrictions. (1)
23 Clinical review criteria used to establish step therapy protocols shall be based on clinical practice
24 guidelines that: (A) That recommend drugs be taken in the specific sequence required by the step
25 therapy protocol. (B) Are developed and endorsed by a multidisciplinary panel of experts that
26 manages conflicts of interest among the members of the writing and review groups by: (i)
27 Requiring members to disclose any potential conflict of interests with entities, including insurers,
28 health plans, and pharmaceutical manufacturers and recuse themselves of voting if they have a
29 conflict of interest. (ii) Using a methodologist to work with writing groups to provide objectivity
30 in data analysis and ranking of evidence through the preparation of evidence tables and
31 facilitating consensus. (iii) Offering opportunities for public review and comments. (C) Are based
32 on high quality studies, research, and medical practice. (D) Are created by an explicit and
33 transparent process that: (i) Minimizes biases and conflicts of interest; (ii) Explains the
34 relationship between treatment options and outcomes; (iii) Rates the quality of the evidence
35 supporting recommendations; and (iv) Considers relevant patient subgroups and preferences. (E)
36 Are continually updated through a review of new evidence, research and newly developed
37 treatments. (2) In the absence of clinical guidelines that meet the requirements in section (1),

38 peer reviewed publications may be substituted. (3) When establishing a step therapy protocol, a
39 utilization review agent shall also take into account the needs of atypical patient populations and
40 diagnoses when establishing clinical review criteria.(4) This section shall not be construed to
41 require insurers, health plans or the state to set up a new entity to develop clinical review criteria
42 used for step therapy protocols.(c) When coverage of medications for the treatment of any
43 medical condition are restricted for use by a carrier or utilization review organization via a step
44 therapy protocol, the patient and prescribing practitioner shall have access to a clear readily
45 accessible and convenient process to request a Step Therapy Exception Determination. A carrier
46 or utilization review organization may use its existing medical exceptions process to satisfy this
47 requirement. The process shall be disclosed to the patient and health care providers, including
48 documenting and making easily accessible on the carriers' or utilization review organization's
49 website.(d) A step therapy override exception determination shall be expeditiously granted if:(1)
50 The required drug is contraindicated or will likely cause an adverse reaction by or physical or
51 mental harm to the patient;(2) The required drug is expected to be ineffective based on the
52 known relevant physical or mental characteristics of the insured and the known characteristics of
53 the drug regimen;(3) The enrollee has tried the step therapy-required drug while under their
54 current or a previous health plan, or another drug in the same pharmacologic class or with the
55 same mechanism of action and such drugs were discontinued due to lack of efficacy or
56 effectiveness, diminished effect, or an adverse event;(4) The patient is stable on a drug
57 recommended by their health care provider for the medical condition under consideration while
58 on a current or previous health insurance or health benefit plan;(5) The step therapy-required
59 drug is not in the best interest of the patient, based on medical appropriateness.(e) Upon the
60 granting of a step therapy override exception determination, the carrier or utilization review

61 organization shall authorize coverage for the drug prescribed by the enrollee’s treating health
62 care provider. (f) The carrier or utilization review organization shall respond to step therapy
63 override exception request or an appeal within seventy two hours of receipt. In cases where
64 exigent circumstances exist a carrier or utilization review organization shall respond within
65 twenty four hours of receipts. Should a response by a carrier or utilization review organization
66 not be received within this time allotted the exception or appeal shall be deemed granted.(g) This
67 section shall not be construed to prevent:(1) A carrier or utilization review organization from
68 requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the
69 equivalent branded drug;(2) A health care provider from prescribing a drug he or she determines
70 is medically appropriate.

71 SECTION ____ . Chapter 176A of the General Laws is hereby amended by inserting after
72 section 8EE the following section:-Section 8FF. (a) As used in this section the following words
73 shall, unless the context clearly requires otherwise, have the following meanings:-“Clinical
74 practice guidelines” means a systematically developed statement to assist practitioner and patient
75 decisions about appropriate healthcare for specific clinical circumstances and
76 conditions.“Clinical review criteria” means the written screening procedures, decision abstracts,
77 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
78 organization to determine the medical necessity and appropriateness of healthcare services.“Step
79 therapy protocol” means a protocol or program that establishes the specific sequence in which
80 prescription drugs for a specified medical condition and medically appropriate for a particular
81 patient and are covered as a pharmacy or medical benefit by a carrier, including self-
82 administered and physician-administered drugs, .“Step Therapy Override Exception
83 Determination” means a determination as to whether step therapy should apply in a particular

84 situation, or whether the step therapy protocol should be overridden in favor of immediate
85 coverage of the patient's and/or prescriber's preferred drug. This determination is based on a
86 review of the patient's and/or prescriber's request for an override, along with supporting
87 rationale and documentation. "Utilization review organization" means an entity that conducts
88 utilization review, other than a health carrier performing utilization review for its own health
89 benefit plans. (b) Any contract between a subscriber and the corporation under an individual or
90 group hospital service plan which is delivered, issued or renewed within the commonwealth that
91 provides coverage for prescription drugs and uses step-therapy protocols shall have the following
92 requirements and restrictions. (1) Clinical review criteria used to establish step therapy protocols
93 shall be based on clinical practice guidelines that: (A) That recommend drugs be taken in the
94 specific sequence required by the step therapy protocol. (B) Are developed and endorsed by a
95 multidisciplinary panel of experts that manages conflicts of interest among the members of the
96 writing and review groups by: (i) Requiring members to disclose any potential conflict of
97 interests with entities, including insurers, health plans, and pharmaceutical manufacturers and
98 reclude themselves of voting if they have a conflict of interest. (ii) Using a methodologist to work
99 with writing groups to provide objectivity in data analysis and ranking of evidence through the
100 preparation of evidence tables and facilitating consensus. (iii) Offering opportunities for public
101 review and comments. (C) Are based on high quality studies, research, and medical practice. (D)
102 Are created by an explicit and transparent process that: (i) Minimizes biases and conflicts of
103 interest; (ii) Explains the relationship between treatment options and outcomes; (iii) Rates the
104 quality of the evidence supporting recommendations; and (iv) Considers relevant patient
105 subgroups and preferences. (E) Are continually updated through a review of new evidence,
106 research and newly developed treatments. (2) In the absence of clinical guidelines that meet the

107 requirements in section (1), peer reviewed publications may be substituted.(3) When establishing
108 a step therapy protocol, a utilization review agent shall also take into account the needs of
109 atypical patient populations and diagnoses when establishing clinical review criteria.(4) This
110 section shall not be construed to require insurers, health plans or the state to set up a new entity
111 to develop clinical review criteria used for step therapy protocols.(c) When coverage of
112 medications for the treatment of any medical condition are restricted for use by a carrier or
113 utilization review organization via a step therapy protocol, the patient and prescribing
114 practitioner shall have access to a clear readily accessible and convenient process to request a
115 Step Therapy Exception Determination. A carrier or utilization review organization may use its
116 existing medical exceptions process to satisfy this requirement. The process shall be disclosed to
117 the patient and health care providers, including documenting and making easily accessible on the
118 carriers' or utilization review organization's website.(d) A step therapy override exception
119 determination shall be expeditiously granted if:(1) The required drug is contraindicated or will
120 likely cause an adverse reaction by or physical or mental harm to the patient;(2) The required
121 drug is expected to be ineffective based on the known relevant physical or mental characteristics
122 of the insured and the known characteristics of the drug regimen;(3) The enrollee has tried the
123 step therapy-required drug while under their current or a previous health plan, or another drug in
124 the same pharmacologic class or with the same mechanism of action and such drugs were
125 discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;(4)
126 The patient is stable on a drug recommended by their health care provider for the medical
127 condition under consideration while on a current or previous health insurance or health benefit
128 plan;(5) The step therapy-required drug is not in the best interest of the patient, based on medical
129 appropriateness.(e) Upon the granting of a step therapy override exception determination, the

130 carrier or utilization review organization shall authorize coverage for the drug prescribed by the
131 enrollee’s treating health care provider.(f) The carrier or utilization review organization shall
132 respond to step therapy override exception request or an appeal within seventy two hours of
133 receipt. In cases where exigent circumstances exist a carrier or utilization review organization
134 shall respond within twenty four hours of receipts. Should a response by a carrier or utilization
135 review organization not be received within this time allotted the exception or appeal shall be
136 deemed granted.(g) This section shall not be construed to prevent:(1) A carrier or utilization
137 review organization from requiring an enrollee try an AB-rated generic equivalent prior to
138 providing reimbursement for the equivalent branded drug;(2) A health care provider from
139 prescribing a drug he or she determines is medically appropriate.

140 SECTION _____. Chapter 176B of the General Laws is hereby amended by inserting after
141 section 4EE the following section:-Section 4FF. (a) As used in this section the following words
142 shall, unless the context clearly requires otherwise, have the following meanings:-“Clinical
143 practice guidelines” means a systematically developed statement to assist practitioner and patient
144 decisions about appropriate healthcare for specific clinical circumstances and
145 conditions.“Clinical review criteria” means the written screening procedures, decision abstracts,
146 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
147 organization to determine the medical necessity and appropriateness of healthcare services.“Step
148 therapy protocol” means a protocol or program that establishes the specific sequence in which
149 prescription drugs for a specified medical condition and medically appropriate for a particular
150 patient and are covered under a health benefit plan as a pharmacy or medical benefit by a carrier,
151 including self-administered and physician-administered drugs.“Step Therapy Override Exception
152 Determination” means a determination as to whether step therapy should apply in a particular

153 situation, or whether the step therapy protocol should be overridden in favor of immediate
154 coverage of the patient's and/or prescriber's preferred drug. This determination is based on a
155 review of the patient's and/or prescriber's request for an override, along with supporting
156 rationale and documentation. "Utilization review organization" means an entity that conducts
157 utilization review, other than a health carrier performing utilization review for its own health
158 benefit plans. (b) Any subscription certificate under an individual or group medical service
159 agreement delivered, issued or renewed within the commonwealth that provides coverage for
160 prescription drugs and uses step-therapy protocols shall have the following requirements and
161 restrictions. (1) Clinical review criteria used to establish step therapy protocols shall be based on
162 clinical practice guidelines that: (A) That recommend drugs be taken in the specific sequence
163 required by the step therapy protocol. (B) Are developed and endorsed by a multidisciplinary
164 panel of experts that manages conflicts of interest among the members of the writing and review
165 groups by: (i) Requiring members to disclose any potential conflict of interests with entities,
166 including insurers, health plans, and pharmaceutical manufacturers and recuse themselves of
167 voting if they have a conflict of interest. (ii) Using a methodologist to work with writing groups
168 to provide objectivity in data analysis and ranking of evidence through the preparation of
169 evidence tables and facilitating consensus. (iii) Offering opportunities for public review and
170 comments. (C) Are based on high quality studies, research, and medical practice. (D) Are created
171 by an explicit and transparent process that: (i) Minimizes biases and conflicts of interest; (ii)
172 Explains the relationship between treatment options and outcomes; (iii) Rates the quality of the
173 evidence supporting recommendations; and (iv) Considers relevant patient subgroups and
174 preferences. (E) Are continually updated through a review of new evidence, research and newly
175 developed treatments. (2) In the absence of clinical guidelines that meet the requirements in

176 section (1), peer reviewed publications may be substituted.(3) When establishing a step therapy
177 protocol, a utilization review agent shall also take into account the needs of atypical patient
178 populations and diagnoses when establishing clinical review criteria.(4) This section shall not be
179 construed to require insurers, health plans or the state to set up a new entity to develop clinical
180 review criteria used for step therapy protocols.(c) When coverage of medications for the
181 treatment of any medical condition are restricted for use by a carrier or utilization review
182 organization via a step therapy protocol, the patient and prescribing practitioner shall have access
183 to a clear readily accessible and convenient process to request a Step Therapy Exception
184 Determination. A carrier or utilization review organization may use its existing medical
185 exceptions process to satisfy this requirement. The process shall be disclosed to the patient and
186 health care providers, including documenting and making easily accessible on the carriers' or
187 utilization review organization's website.(d) A step therapy override exception determination
188 shall be expeditiously granted if:(1) The required drug is contraindicated or will likely cause an
189 adverse reaction by or physical or mental harm to the patient;(2) The required drug is expected to
190 be ineffective based on the known relevant physical or mental characteristics of the insured and
191 the known characteristics of the drug regimen;(3) The enrollee has tried the step therapy-required
192 drug while under their current or a previous health plan, or another drug in the same
193 pharmacologic class or with the same mechanism of action and such drugs were discontinued
194 due to lack of efficacy or effectiveness, diminished effect, or an adverse event;(4) The patient is
195 stable on a drug recommended by their health care provider for the medical condition under
196 consideration while on a current or previous health insurance or health benefit plan;(5) The step
197 therapy-required drug is not in the best interest of the patient, based on medical
198 appropriateness.(e) Upon the granting of a step therapy override exception determination, the

199 carrier or utilization review organization shall authorize coverage for the drug prescribed by the
200 enrollee’s treating health care provider.(f) The carrier or utilization review organization shall
201 respond to step therapy override exception request or an appeal within seventy two hours of
202 receipt. In cases where exigent circumstances exist a carrier or utilization review organization
203 shall respond within twenty four hours of receipts. Should a response by a carrier or utilization
204 review organization not be received within this time allotted the exception or appeal shall be
205 deemed granted.(g) This section shall not be construed to prevent:(1) A carrier or utilization
206 review organization from requiring an enrollee try an AB-rated generic equivalent prior to
207 providing reimbursement for the equivalent branded drug;(2) A health care provider from
208 prescribing a drug he or she determines is medically appropriate.

209 SECTION ____ . Chapter 176G of the General Laws is hereby amended by inserting after
210 section 4W the following section:-Section 4X. (a) As used in this section the following words
211 shall, unless the context clearly requires otherwise, have the following meanings:“Clinical
212 practice guidelines” means a systematically developed statement to assist practitioner and patient
213 decisions about appropriate healthcare for specific clinical circumstances and
214 conditions.“Clinical review criteria” means the written screening procedures, decision abstracts,
215 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review
216 organization to determine the medical necessity and appropriateness of healthcare services.“Step
217 therapy protocol” means a protocol or program that establishes the specific sequence in which
218 prescription drugs for a specified medical condition and medically appropriate for a particular
219 patient and are covered under a health benefit plan as a pharmacy or medical benefit by a carrier,
220 including self-administered and physician-administered drugs, .“Step Therapy Override
221 Exception Determination” means a determination as to whether step therapy should apply in a

222 particular situation, or whether the step therapy protocol should be overridden in favor of
223 immediate coverage of the patient’s and/or prescriber’s preferred drug. This determination is
224 based on a review of the patient’s and/or prescriber’s request for an override, along with
225 supporting rationale and documentation. “Utilization review organization” means an entity that
226 conducts utilization review, other than a health carrier performing utilization review for its own
227 health benefit plans. (b) Any individual or group health maintenance that provides coverage for
228 prescription drugs and uses step-therapy protocols shall have the following requirements and
229 restrictions. (1) Clinical review criteria used to establish step therapy protocols shall be based on
230 clinical practice guidelines that: (A) That recommend drugs be taken in the specific sequence
231 required by the step therapy protocol. (B) Are developed and endorsed by a multidisciplinary
232 panel of experts that manages conflicts of interest among the members of the writing and review
233 groups by: (i) Requiring members to disclose any potential conflict of interests with entities,
234 including insurers, health plans, and pharmaceutical manufacturers and recuse themselves of
235 voting if they have a conflict of interest. (ii) Using a methodologist to work with writing groups
236 to provide objectivity in data analysis and ranking of evidence through the preparation of
237 evidence tables and facilitating consensus. (iii) Offering opportunities for public review and
238 comments. (C) Are based on high quality studies, research, and medical practice. (D) Are created
239 by an explicit and transparent process that: (i) Minimizes biases and conflicts of interest; (ii)
240 Explains the relationship between treatment options and outcomes; (iii) Rates the quality of the
241 evidence supporting recommendations; and (iv) Considers relevant patient subgroups and
242 preferences. (E) Are continually updated through a review of new evidence, research and newly
243 developed treatments. (2) In the absence of clinical guidelines that meet the requirements in
244 section (1), peer reviewed publications may be substituted. (3) When establishing a step therapy

245 protocol, a utilization review agent shall also take into account the needs of atypical patient
246 populations and diagnoses when establishing clinical review criteria.(4) This section shall not be
247 construed to require insurers, health plans or the state to set up a new entity to develop clinical
248 review criteria used for step therapy protocols.(c) When coverage of medications for the
249 treatment of any medical condition are restricted for use by a carrier or utilization review
250 organization via a step therapy protocol, the patient and prescribing practitioner shall have access
251 to a clear readily accessible and convenient process to request a Step Therapy Exception
252 Determination. A carrier or utilization review organization may use its existing medical
253 exceptions process to satisfy this requirement. The process shall be disclosed to the patient and
254 health care providers, including documenting and making easily accessible on the carriers' or
255 utilization review organization's website.(d) A step therapy override exception determination
256 shall be expeditiously granted if:(1) The required drug is contraindicated or will likely cause an
257 adverse reaction by or physical or mental harm to the patient;(2) The required drug is expected to
258 be ineffective based on the known relevant physical or mental characteristics of the insured and
259 the known characteristics of the drug regimen;(3) The enrollee has tried the step therapy-required
260 drug while under their current or a previous health plan, or another drug in the same
261 pharmacologic class or with the same mechanism of action and such drugs were discontinued
262 due to lack of efficacy or effectiveness, diminished effect, or an adverse event;(4) The patient is
263 stable on a drug recommended by their health care provider for the medical condition under
264 consideration while on a current or previous health insurance or health benefit plan;(5) The step
265 therapy-required drug is not in the best interest of the patient, based on medical
266 appropriateness.(e) Upon the granting of a step therapy override exception determination, the
267 carrier or utilization review organization shall authorize coverage for the drug prescribed by the

268 enrollee's treating health care provider.(f) The carrier or utilization review organization shall
269 respond to step therapy override exception request or an appeal within seventy two hours of
270 receipt. In cases where exigent circumstances exist a carrier or utilization review organization
271 shall respond within twenty four hours of receipts. Should a response by a carrier or utilization
272 review organization not be received within this time allotted the exception or appeal shall be
273 deemed granted.(g) This section shall not be construed to prevent:(1) A carrier or utilization
274 review organization from requiring an enrollee try an AB-rated generic equivalent prior to
275 providing reimbursement for the equivalent branded drug;(2) A health care provider from
276 prescribing a drug he or she determines is medically appropriate.

277 SECTION ____ . Sections 1 to 5, inclusive, shall apply to all policies, contracts and
278 certificates of health insurance subject to section 17K of chapter 32A, section 47CC of chapter
279 175, section 8FF of chapter 176A, section 4FF of chapter 176B and section 4X of chapter 176G
280 of the General Laws which are delivered, issued or renewed on or after January 1, 20XX.”