

**SENATE . . . . . No. 551**

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PRESENTED BY:

***Barbara A. L'Italien***

*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 reducing health care costs through improved medication management.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	
<i>Barbara A. L'Italien</i>	<i>Second Essex and Middlesex</i>	
<i>Brian M. Ashe</i>	<i>2nd Hampden</i>	<i>2/1/2017</i>
<i>Denise Provost</i>	<i>27th Middlesex</i>	<i>2/3/2017</i>
<i>Anne M. Gobi</i>	<i>Worcester, Hampden, Hampshire and Middlesex</i>	<i>2/3/2017</i>
<i>Eileen M. Donoghue</i>	<i>First Middlesex</i>	<i>3/31/2017</i>

**SENATE . . . . . No. 551**

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By Ms. L'Italien, a petition (accompanied by bill, Senate, No. 551) of Barbara A. L'Italien, Brian M. Ashe, Denise Provost and Anne M. Gobi for legislation to reduce health care costs through improved medication management. Financial Services.

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**In the One Hundred and Ninetieth General Court  
(2017-2018)**  
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An Act reducing health care costs through improved medication management.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

127 (i) Minimizes biases and conflicts of interest;

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

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

130 (iv) Considers relevant patient subgroups and preferences.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

213 (i) Minimizes biases and conflicts of interest;

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

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

216 (iv) Considers relevant patient subgroups and preferences.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

298 (i) Minimizes biases and conflicts of interest;

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

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

301 (iv) Considers relevant patient subgroups and preferences.

302 (E) Are continually updated through a review of new evidence, research and newly

303 developed treatments.

304 (2) In the absence of clinical guidelines that meet the requirements in section (1), peer

305 reviewed publications may be substituted.

306 (3) When establishing a step therapy protocol, a utilization review agent shall also take

307 into account the needs of atypical patient populations and diagnoses when establishing clinical

308 review criteria.

309 (4) This section shall not be construed to require insurers, health plans or the state to set

310 up a new entity to develop clinical review criteria used for step therapy protocols.

311 (c) When coverage of medications for the treatment of any medical condition are

312 restricted for use by a carrier or utilization review organization via a step therapy protocol, the

313 patient and prescribing practitioner shall have access to a clear readily accessible and convenient

314 process to request a Step Therapy Exception Determination. A carrier or utilization review

315 organization may use its existing medical exceptions process to satisfy this requirement. The

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

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

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

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

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

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

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

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

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

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

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

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

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

345 SECTION 5. Sections 1 to 5, inclusive, shall apply to all policies, contracts and  
346 certificates of health insurance subject to section 17K of chapter 32A, section 47CC of chapter  
347 175, section 8FF of chapter 176A, section 4FF of chapter 176B and section 4X of chapter 176G  
348 of the General Laws which are delivered, issued or renewed on or after January 1, 20XX.