

**HOUSE . . . . . No. 949**

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**The Commonwealth of Massachusetts**

PRESENTED BY:

*Michael S. Day*

*To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:*

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to non-medical switching.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
<i>Michael S. Day</i>	<i>31st Middlesex</i>
<i>Steven Ultrino</i>	<i>33rd Middlesex</i>
<i>Christopher Hendricks</i>	<i>11th Bristol</i>
<i>Kimberly N. Ferguson</i>	<i>1st Worcester</i>

**HOUSE . . . . . No. 949**

By Mr. Day of Stoneham, a petition (accompanied by bill, House, No. 949) of Michael S. Day and others relative to changes to health benefit plans that cause certain covered persons to switch to less costly alternate prescription drugs. Financial Services.

**The Commonwealth of Massachusetts**

**In the One Hundred and Ninety-First General Court  
(2019-2020)**

An Act relative to non-medical switching.

*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, as appearing in the 2016 Official Edition, is  
2 hereby amended by inserting after section 229 the following section:-

3 Section 230.

4 1. Definitions. For the purpose of this section:

5 a. "Commissioner" means the commissioner of insurance.

6 b. "Cost sharing" means any coverage limit, copayment, coinsurance, deductible, or  
7 other out-of-pocket expense requirement.

8 c. "Coverage exemption" means a determination made by a health carrier, health benefit  
9 plan, or utilization review organization to cover a prescription drug that is otherwise excluded  
10 from coverage.

11 d. "Coverage exemption determination" means a determination made by a health carrier,  
12 health benefit plan, or utilization review organization whether to cover a prescription drug that is  
13 otherwise excluded from coverage.

14 e. "Covered person" means the same as defined in section 1 of Chapter 176J.

15 f. "Discontinued health benefit plan" means a covered person's existing health benefit  
16 plan that is discontinued by a health carrier during open enrollment for the next plan year.

17 g. "Formulary" means a complete list of prescription drugs eligible for coverage under a  
18 health benefit plan.

19 h. "Health benefit plan" means the same as defined in section 1 of Chapter 176 J.

20 i. "Health care professional" means the same as defined in section 1 of Chapter 176O.

21 j. "Health care services" means the same as defined in section 1 of Chapter 176O.

22 k. "Health carrier" means the same as defined in section 1 of Chapter 176O.

23 l. "Nonmedical switching" means a health benefit plan's restrictive changes to the health  
24 benefit plan's formulary after the current plan year has begun or during the open enrollment  
25 period for the upcoming plan year, causing a covered person who is medically stable on the  
26 covered person's current prescribed drug, inclusive of changes to the drug dosage, as determined  
27 by the prescribing health care professional, to switch to a less costly alternate prescription drug.

28 m. "Open enrollment" means the yearly time period an individual can enroll in a health  
29 benefit plan.

30 n. "Utilization review" means the same as defined in section 1 of Chapter 176O.

31 o. "Utilization review organization" means the same as defined in section 1 1 of Chapter  
32 176O.

33 2. Nonmedical switching. With respect to a health carrier that has entered into a health  
34 benefit plan with a covered person that covers prescription drug benefits, all of the following  
35 apply:

36 a. A health carrier, health benefit plan, or utilization review organization shall not limit  
37 or exclude coverage of a prescription drug for any covered person who is medically stable on  
38 such drug as determined by the prescribing health care professional, if all of the following apply:

39 (1) The prescription drug was previously approved by the health carrier for coverage for  
40 the covered person.

41 (2) The covered person's prescribing health care professional has prescribed the drug for  
42 the medical condition within the previous six months.

43 (3) The covered person continues to be an enrollee of the health benefit plan.

44 b. Coverage of a covered person's prescription drug, as described in paragraph "a", shall  
45 continue through the last day of the covered person's eligibility under the health benefit plan,  
46 inclusive of any open enrollment period.

47 c. Prohibited limitations and exclusions referred to in paragraph "a" include but are not  
48 limited to the following:

49 (1) Limiting or reducing the maximum coverage of prescription drug benefits.

50 (2) Increasing cost sharing for a covered prescription drug.

51 (3) Moving a prescription drug to a more restrictive tier if the health carrier uses a  
52 formulary with tiers.

53 (4) Removing a prescription drug from a formulary, unless the United States food and  
54 drug administration has issued a statement about the drug that calls into question the clinical  
55 safety of the drug, or the manufacturer of the drug has notified the United States food and drug  
56 administration of a manufacturing discontinuance or potential discontinuance of the drug as  
57 required by section 506C of the Federal Food, Drug, and Cosmetic Act, as codified in 21 U.S.C.  
58 §356c.

59 3. Coverage exemption determination process.

60 a. To ensure continuity of care, a health carrier, health plan, or utilization review  
61 organization shall provide a covered person and prescribing health care professional with access  
62 to a clear and convenient process to request a coverage exemption determination. A health  
63 carrier, health plan, or utilization review organization may use its existing medical exceptions  
64 process to satisfy this requirement. The process used shall be easily accessible on the internet site  
65 of the health carrier, health benefit plan, or utilization review organization.

66 b. A health carrier, health benefit plan, or utilization review organization shall respond to  
67 a coverage exemption determination request within seventy-two hours of receipt. In cases where  
68 exigent circumstances exist, a health carrier, health benefit plan, or utilization review  
69 organization shall respond within twenty-four hours of receipt. If a response by a health carrier,  
70 health benefit plan, or utilization review organization is not received within the applicable time  
71 period, the coverage exemption shall be deemed granted.

72 (1) A coverage exemption shall be expeditiously granted for a discontinued health  
73 benefit plan if a covered person enrolls in a comparable plan offered by the same health carrier,  
74 and all of the following conditions apply:

75 (a) The covered person is medically stable on a prescription drug as determined by the  
76 prescribing health care professional.

77 (b) The prescribing health care professional continues to prescribe the drug for the  
78 covered person for the medical condition.

79 (c) In comparison to the discontinued health benefit plan, the new health benefit plan  
80 does any of the following:

81 (i) Limits or reduces the maximum coverage of prescription drug benefits.

82 (ii) Increases cost sharing for the prescription drug.

83 (iii) Moves the prescription drug to a more restrictive tier if the health carrier uses a  
84 formulary with tiers.

85 (iv) Excludes the prescription drug from the formulary.

86 c. Upon granting of a coverage exemption for a drug prescribed by a covered person's  
87 prescribing health care professional, a health carrier, health benefit plan, or utilization review  
88 organization shall authorize coverage no more restrictive than that offered in a discontinued  
89 health benefit plan, or than that offered prior to implementation of restrictive changes to the  
90 health benefit plan's formulary after the current plan year began.

91 d. If a determination is made to deny a request for a coverage exemption, the health  
92 carrier, health benefit plan, or utilization review organization shall provide the covered person or  
93 the covered person's authorized representative and the authorized person's prescribing health  
94 care professional with the reason for denial and information regarding the procedure to appeal  
95 the denial. Any determination to deny a coverage exemption may be appealed by a covered  
96 person or the covered person's authorized representative.

97 e. A health carrier, health benefit plan, or utilization review organization shall uphold or  
98 reverse a determination to deny a coverage exemption within seventy-two hours of receipt of an  
99 appeal of denial. In cases where exigent circumstances exist, a health carrier, health benefit plan,  
100 or utilization review organization shall uphold or reverse a determination to deny a coverage  
101 exemption within twenty-four hours of receipt. If the determination to deny a coverage  
102 exemption is not upheld or reversed on appeal within the applicable time period, the denial shall  
103 be deemed reversed and the coverage exemption shall be deemed approved.

104 f. If a determination to deny a coverage exemption is upheld on appeal, the health  
105 carrier, health benefit plan, or utilization review organization shall provide the covered person or  
106 covered person's authorized representative and the covered person's prescribing health care  
107 professional with the reason for upholding the denial on appeal and information regarding the  
108 procedure to request external review of the denial pursuant to chapter 514J. Any denial of a  
109 request for a coverage exemption that is upheld on appeal shall be considered a final adverse  
110 determination for purposes of chapter 514J and is eligible for a request for external review by a  
111 covered person or the covered person's authorized representative pursuant to chapter 514J.

112 4. Limitations. This section shall not be construed to do any of the following:

113 a. Prevent a health care professional from prescribing another drug covered by the health  
114 carrier that the health care professional deems medically necessary for the covered person.

115 b. Prevent a health carrier from doing any of the following:

116 (1) Adding a prescription drug to its formulary.

117 (2) Removing a prescription drug from its formulary if the drug manufacturer has  
118 removed the drug for sale in the United States.

119 (3) Requiring a pharmacist to effect a substitution of a generic or interchangeable  
120 biological drug product pursuant to section 12EE Chapter 112.

121 5. Enforcement. The commissioner may take any enforcement action under the  
122 commissioner's authority to enforce compliance with this section.

123 6. Applicability. This section is applicable to a health benefit plan that is delivered,  
124 issued for delivery, continued, or renewed in this state on or after January 1, 2019.

125 Section 2. Chapter 176A of the General Laws, as appearing in the 2016 Official Edition,  
126 is hereby amended by inserting after section 37 the following section:-

127 Section 38.

128 1. Definitions. For the purpose of this section:

129 a. "Commissioner" means the commissioner of insurance.

130 b. "Cost sharing" means any coverage limit, copayment, coinsurance, deductible, or  
131 other out-of-pocket expense requirement.



132 c. “Coverage exemption” means a determination made by a health carrier, health benefit  
133 plan, or utilization review organization to cover a prescription drug that is otherwise excluded  
134 from coverage.

135 d. “Coverage exemption determination” means a determination made by a health carrier,  
136 health benefit plan, or utilization review organization whether to cover a prescription drug that is  
137 otherwise excluded from coverage.

138 e. “Covered person” means the same as defined in section 1 of Chapter 176I.

139 f. “Discontinued health benefit plan” means a covered person’s existing health benefit  
140 plan that is discontinued by a health carrier during open enrollment for the next plan year.

141 g. “Formulary” means a complete list of prescription drugs eligible for coverage under a  
142 health benefit plan.

143 h. “Health benefit plan” means the same as defined in section 1 of Chapter 176I.

144 i. “Health care professional” means the same as defined in section 1 of Chapter 176O.

145 j. “Health care services” means the same as defined in section 1 of Chapter 176O.

146 k. “Health carrier” means the same as defined in section 1 of Chapter 176O.

147 l. “Nonmedical switching” means a health benefit plan’s restrictive changes to the health  
148 benefit plan’s formulary after the current plan year has begun or during the open enrollment  
149 period for the upcoming plan year, causing a covered person who is medically stable on the  
150 covered person’s current prescribed drug, inclusive of changes to the drug dosage, as determined  
151 by the prescribing health care professional, to switch to a less costly alternate prescription drug.

152 m. “Open enrollment” means the yearly time period an individual can enroll in a health  
153 benefit plan.

154 n. “Utilization review” means the same as defined in section 1 of Chapter 176O.

155 o. “Utilization review organization” means the same as defined in section 1 of Chapter  
156 176O.

157 2. Nonmedical switching. With respect to a health carrier that has entered into a health  
158 benefit plan with a covered person that covers prescription drug benefits, all of the following  
159 apply:

160 a. A health carrier, health benefit plan, or utilization review organization shall not limit  
161 or exclude coverage of a prescription drug for any covered person who is medically stable on  
162 such drug as determined by the prescribing health care professional, if all of the following apply:

163 (1) The prescription drug was previously approved by the health carrier for coverage for  
164 the covered person.

165 (2) The covered person’s prescribing health care professional has prescribed the drug for  
166 the medical condition within the previous six months.

167 (3) The covered person continues to be an enrollee of the health benefit plan.

168 b. Coverage of a covered person’s prescription drug, as described in paragraph “a”, shall  
169 continue through the last day of the covered person’s eligibility under the health benefit plan,  
170 inclusive of any open enrollment period.

171 c. Prohibited limitations and exclusions referred to in paragraph “a” include but are not  
172 limited to the following:

173 (1) Limiting or reducing the maximum coverage of prescription drug benefits.

174 (2) Increasing cost sharing for a covered prescription drug.

175 (3) Moving a prescription drug to a more restrictive tier if the health carrier uses a  
176 formulary with tiers.

177 (4) Removing a prescription drug from a formulary, unless the United States food and  
178 drug administration has issued a statement about the drug that calls into question the clinical  
179 safety of the drug, or the manufacturer of the drug has notified the United States food and drug  
180 administration of a manufacturing discontinuance or potential discontinuance of the drug as  
181 required by section 506C of the Federal Food, Drug, and Cosmetic Act, as codified in 21 U.S.C.  
182 §356c.

183 3. Coverage exemption determination process.

184 a. To ensure continuity of care, a health carrier, health plan, or utilization review  
185 organization shall provide a covered person and prescribing health care professional with access  
186 to a clear and convenient process to request a coverage exemption determination. A health  
187 carrier, health plan, or utilization review organization may use its existing medical exceptions  
188 process to satisfy this requirement. The process used shall be easily accessible on the internet site  
189 of the health carrier, health benefit plan, or utilization review organization.

190 b. A health carrier, health benefit plan, or utilization review organization shall respond to  
191 a coverage exemption determination request within seventy-two hours of receipt. In cases where

192 exigent circumstances exist, a health carrier, health benefit plan, or utilization review  
193 organization shall respond within twenty-four hours of receipt. If a response by a health carrier,  
194 health benefit plan, or utilization review organization is not received within the applicable time  
195 period, the coverage exemption shall be deemed granted.

196 (1) A coverage exemption shall be expeditiously granted for a discontinued health  
197 benefit plan if a covered person enrolls in a comparable plan offered by the same health carrier,  
198 and all of the following conditions apply:

199 (a) The covered person is medically stable on a prescription drug as determined by the  
200 prescribing health care professional.

201 (b) The prescribing health care professional continues to prescribe the drug for the  
202 covered person for the medical condition.

203 (c) In comparison to the discontinued health benefit plan, the new health benefit plan  
204 does any of the following:

205 (i) Limits or reduces the maximum coverage of prescription drug benefits.

206 (ii) Increases cost sharing for the prescription drug.

207 (iii) Moves the prescription drug to a more restrictive tier if the health carrier uses a  
208 formulary with tiers.

209 (iv) Excludes the prescription drug from the formulary.

210 c. Upon granting of a coverage exemption for a drug prescribed by a covered person's  
211 prescribing health care professional, a health carrier, health benefit plan, or utilization review

212 organization shall authorize coverage no more restrictive than that offered in a discontinued  
213 health benefit plan, or than that offered prior to implementation of restrictive changes to the  
214 health benefit plan's formulary after the current plan year began.

215 d. If a determination is made to deny a request for a coverage exemption, the health  
216 carrier, health benefit plan, or utilization review organization shall provide the covered person or  
217 the covered person's authorized representative and the authorized person's prescribing health  
218 care professional with the reason for denial and information regarding the procedure to appeal  
219 the denial. Any determination to deny a coverage exemption may be appealed by a covered  
220 person or the covered person's authorized representative.

221 e. A health carrier, health benefit plan, or utilization review organization shall uphold or  
222 reverse a determination to deny a coverage exemption within seventy-two hours of receipt of an  
223 appeal of denial. In cases where exigent circumstances exist, a health carrier, health benefit plan,  
224 or utilization review organization shall uphold or reverse a determination to deny a coverage  
225 exemption within twenty-four hours of receipt. If the determination to deny a coverage  
226 exemption is not upheld or reversed on appeal within the applicable time period, the denial shall  
227 be deemed reversed and the coverage exemption shall be deemed approved.

228 f. If a determination to deny a coverage exemption is upheld on appeal, the health  
229 carrier, health benefit plan, or utilization review organization shall provide the covered person or  
230 covered person's authorized representative and the covered person's prescribing health care  
231 professional with the reason for upholding the denial on appeal and information regarding the  
232 procedure to request external review of the denial pursuant to chapter 514J. Any denial of a  
233 request for a coverage exemption that is upheld on appeal shall be considered a final adverse

234 determination for purposes of chapter 514J and is eligible for a request for external review by a  
235 covered person or the covered person's authorized representative pursuant to chapter 514J.

236 4. Limitations. This section shall not be construed to do any of the following:

237 a. Prevent a health care professional from prescribing another drug covered by the health  
238 carrier that the health care professional deems medically necessary for the covered person.

239 b. Prevent a health carrier from doing any of the following:

240 (1) Adding a prescription drug to its formulary.

241 (2) Removing a prescription drug from its formulary if the drug manufacturer has  
242 removed the drug for sale in the United States.

243 (3) Requiring a pharmacist to effect a substitution of a generic or interchangeable  
244 biological drug product pursuant to section section 12EE of Chapter 112.

245 5. Enforcement. The commissioner may take any enforcement action under the  
246 commissioner's authority to enforce compliance with this section.

247 6. Applicability. This section is applicable to a health benefit plan that is delivered,  
248 issued for delivery, continued, or renewed in this state on or after January 1, 2019.

249 Section 3. Chapter 176B of the General Laws, as appearing in the 2016 Official Edition,  
250 is hereby amended by inserting after section 24 the following section:-

251 Section 25.

252 1. Definitions. For the purpose of this section:

- 253 a. “Commissioner” means the commissioner of insurance.
- 254 b. “Cost sharing” means any coverage limit, copayment, coinsurance, deductible, or  
255 other out-of-pocket expense requirement.
- 256 c. “Coverage exemption” means a determination made by a health carrier, health benefit  
257 plan, or utilization review organization to cover a prescription drug that is otherwise excluded  
258 from coverage.
- 259 d. “Coverage exemption determination” means a determination made by a health carrier,  
260 health benefit plan, or utilization review organization whether to cover a prescription drug that is  
261 otherwise excluded from coverage.
- 262 e. “Covered person” means the same as defined in section 1 of Chapter 176I.
- 263 f. “Discontinued health benefit plan” means a covered person’s existing health benefit  
264 plan that is discontinued by a health carrier during open enrollment for the next plan year.
- 265 g. “Formulary” means a complete list of prescription drugs eligible for coverage under a  
266 health benefit plan.
- 267 h. “Health benefit plan” means the same as defined in section 1 of Chapter 176I.
- 268 i. “Health care professional” means the same as defined in section 1 of Chapter 176O.
- 269 j. “Health care services” means the same as defined in section 1 of Chapter 176O.
- 270 k. “Health carrier” means the same as defined in section 1 of Chapter 176O.

271           l. “Nonmedical switching” means a health benefit plan’s restrictive changes to the health  
272 benefit plan’s formulary after the current plan year has begun or during the open enrollment  
273 period for the upcoming plan year, causing a covered person who is medically stable on the  
274 covered person’s current prescribed drug, inclusive of changes to the drug dosage, as determined  
275 by the prescribing health care professional, to switch to a less costly alternate prescription drug.

276           m. “Open enrollment” means the yearly time period an individual can enroll in a health  
277 benefit plan.

278           n. “Utilization review” means the same as defined in section 1 of Chapter 176O.

279           o. “Utilization review organization” means the same as defined in section 1 of Chapter  
280 176O.

281           2. Nonmedical switching. With respect to a health carrier that has entered into a health  
282 benefit plan with a covered person that covers prescription drug benefits, all of the following  
283 apply:

284           a. A health carrier, health benefit plan, or utilization review organization shall not limit  
285 or exclude coverage of a prescription drug for any covered person who is medically stable on  
286 such drug as determined by the prescribing health care professional, if all of the following apply:

287           (1) The prescription drug was previously approved by the health carrier for coverage for  
288 the covered person.

289           (2) The covered person’s prescribing health care professional has prescribed the drug for  
290 the medical condition within the previous six months.

291           (3) The covered person continues to be an enrollee of the health benefit plan.



292           b. Coverage of a covered person’s prescription drug, as described in paragraph “a”, shall  
293 continue through the last day of the covered person’s eligibility under the health benefit plan,  
294 inclusive of any open enrollment period.

295           c. Prohibited limitations and exclusions referred to in paragraph “a” include but are not  
296 limited to the following:

297           (1) Limiting or reducing the maximum coverage of prescription drug benefits.

298           (2) Increasing cost sharing for a covered prescription drug.

299           (3) Moving a prescription drug to a more restrictive tier if the health carrier uses a  
300 formulary with tiers.

301           (4) Removing a prescription drug from a formulary, unless the United States food and  
302 drug administration has issued a statement about the drug that calls into question the clinical  
303 safety of the drug, or the manufacturer of the drug has notified the United States food and drug  
304 administration of a manufacturing discontinuance or potential discontinuance of the drug as  
305 required by section 506C of the Federal Food, Drug, and Cosmetic Act, as codified in 21 U.S.C.  
306 §356c.

307           3. Coverage exemption determination process.

308           a. To ensure continuity of care, a health carrier, health plan, or utilization review  
309 organization shall provide a covered person and prescribing health care professional with access  
310 to a clear and convenient process to request a coverage exemption determination. A health  
311 carrier, health plan, or utilization review organization may use its existing medical exceptions

312 process to satisfy this requirement. The process used shall be easily accessible on the internet site  
313 of the health carrier, health benefit plan, or utilization review organization.

314 b. A health carrier, health benefit plan, or utilization review organization shall respond to  
315 a coverage exemption determination request within seventy-two hours of receipt. In cases where  
316 exigent circumstances exist, a health carrier, health benefit plan, or utilization review  
317 organization shall respond within twenty-four hours of receipt. If a response by a health carrier,  
318 health benefit plan, or utilization review organization is not received within the applicable time  
319 period, the coverage exemption shall be deemed granted.

320 (1) A coverage exemption shall be expeditiously granted for a discontinued health  
321 benefit plan if a covered person enrolls in a comparable plan offered by the same health carrier,  
322 and all of the following conditions apply:

323 (a) The covered person is medically stable on a prescription drug as determined by the  
324 prescribing health care professional.

325 (b) The prescribing health care professional continues to prescribe the drug for the  
326 covered person for the medical condition.

327 (c) In comparison to the discontinued health benefit plan, the new health benefit plan  
328 does any of the following:

329 (i) Limits or reduces the maximum coverage of prescription drug benefits.

330 (ii) Increases cost sharing for the prescription drug.

331 (iii) Moves the prescription drug to a more restrictive tier if the health carrier uses a  
332 formulary with tiers.

333 (iv) Excludes the prescription drug from the formulary.

334 c. Upon granting of a coverage exemption for a drug prescribed by a covered person's  
335 prescribing health care professional, a health carrier, health benefit plan, or utilization review  
336 organization shall authorize coverage no more restrictive than that offered in a discontinued  
337 health benefit plan, or than that offered prior to implementation of restrictive changes to the  
338 health benefit plan's formulary after the current plan year began.

339 d. If a determination is made to deny a request for a coverage exemption, the health  
340 carrier, health benefit plan, or utilization review organization shall provide the covered person or  
341 the covered person's authorized representative and the authorized person's prescribing health  
342 care professional with the reason for denial and information regarding the procedure to appeal  
343 the denial. Any determination to deny a coverage exemption may be appealed by a covered  
344 person or the covered person's authorized representative.

345 e. A health carrier, health benefit plan, or utilization review organization shall uphold or  
346 reverse a determination to deny a coverage exemption within seventy-two hours of receipt of an  
347 appeal of denial. In cases where exigent circumstances exist, a health carrier, health benefit plan,  
348 or utilization review organization shall uphold or reverse a determination to deny a coverage  
349 exemption within twenty-four hours of receipt. If the determination to deny a coverage  
350 exemption is not upheld or reversed on appeal within the applicable time period, the denial shall  
351 be deemed reversed and the coverage exemption shall be deemed approved.

352 f. If a determination to deny a coverage exemption is upheld on appeal, the health  
353 carrier, health benefit plan, or utilization review organization shall provide the covered person or  
354 covered person's authorized representative and the covered person's prescribing health care

355 professional with the reason for upholding the denial on appeal and information regarding the  
356 procedure to request external review of the denial pursuant to chapter 514J. Any denial of a  
357 request for a coverage exemption that is upheld on appeal shall be considered a final adverse  
358 determination for purposes of chapter 514J and is eligible for a request for external review by a  
359 covered person or the covered person's authorized representative pursuant to chapter 514J.

360 4. Limitations. This section shall not be construed to do any of the following:

361 a. Prevent a health care professional from prescribing another drug covered by the health  
362 carrier that the health care professional deems medically necessary for the covered person.

363 b. Prevent a health carrier from doing any of the following:

364 (1) Adding a prescription drug to its formulary.

365 (2) Removing a prescription drug from its formulary if the drug manufacturer has  
366 removed the drug for sale in the United States.

367 (3) Requiring a pharmacist to effect a substitution of a generic or interchangeable  
368 biological drug product pursuant to section 12EE of Chapter 112.

369 5. Enforcement. The commissioner may take any enforcement action under the  
370 commissioner's authority to enforce compliance with this section.

371 6. Applicability. This section is applicable to a health benefit plan that is delivered,  
372 issued for delivery, continued, or renewed in this state on or after January 1, 2019.

373 Section 4. Chapter 1776G of the General Laws, as appearing in the 2016 Official Edition,  
374 is hereby amended by inserting after section 32 the following section:-

375 Section 33.

376 1. Definitions. For the purpose of this section:

377 a. “Commissioner” means the commissioner of insurance.

378 b. “Cost sharing” means any coverage limit, copayment, coinsurance, deductible, or  
379 other out-of-pocket expense requirement.

380 c. “Coverage exemption” means a determination made by a health carrier, health benefit  
381 plan, or utilization review organization to cover a prescription drug that is otherwise excluded  
382 from coverage.

383 d. “Coverage exemption determination” means a determination made by a health carrier,  
384 health benefit plan, or utilization review organization whether to cover a prescription drug that is  
385 otherwise excluded from coverage.

386 e. “Covered person” means the same as defined in section 1 of Chapter 176J.

387 f. “Discontinued health benefit plan” means a covered person’s existing health benefit  
388 plan that is discontinued by a health carrier during open enrollment for the next plan year.

389 g. “Formulary” means a complete list of prescription drugs eligible for coverage under a  
390 health benefit plan.

391 h. “Health benefit plan” means the same as defined in section 1 of Chapter 176J.

392 i. “Health care professional” means the same as defined in section 1 of Chapter 176O.

393 j. “Health care services” means the same as defined in section 1 of Chapter 176O.

394 k. “Health carrier” means the same as defined in section 1 of Chapter 176O.

395 l. “Nonmedical switching” means a health benefit plan’s restrictive changes to the health  
396 benefit plan’s formulary after the current plan year has begun or during the open enrollment  
397 period for the upcoming plan year, causing a covered person who is medically stable on the  
398 covered person’s current prescribed drug, inclusive of changes to the drug dosage, as determined  
399 by the prescribing health care professional, to switch to a less costly alternate prescription drug.

400 m. “Open enrollment” means the yearly time period an individual can enroll in a health  
401 benefit plan.

402 n. “Utilization review” means the same as defined in section 1 of Chapter 176O.

403 o. “Utilization review organization” means the same as defined in section 1 of Chapter  
404 176O.

405 2. Nonmedical switching. With respect to a health carrier that has entered into a health  
406 benefit plan with a covered person that covers prescription drug benefits, all of the following  
407 apply:

408 a. A health carrier, health benefit plan, or utilization review organization shall not limit  
409 or exclude coverage of a prescription drug for any covered person who is medically stable on  
410 such drug as determined by the prescribing health care professional, if all of the following apply:

411 (1) The prescription drug was previously approved by the health carrier for coverage for  
412 the covered person.

413 (2) The covered person’s prescribing health care professional has prescribed the drug for  
414 the medical condition within the previous six months.

415 (3) The covered person continues to be an enrollee of the health benefit plan.

416 b. Coverage of a covered person's prescription drug, as described in paragraph "a", shall  
417 continue through the last day of the covered person's eligibility under the health benefit plan,  
418 inclusive of any open enrollment period.

419 c. Prohibited limitations and exclusions referred to in paragraph "a" include but are not  
420 limited to the following:

421 (1) Limiting or reducing the maximum coverage of prescription drug benefits.

422 (2) Increasing cost sharing for a covered prescription drug.

423 (3) Moving a prescription drug to a more restrictive tier if the health carrier uses a  
424 formulary with tiers.

425 (4) Removing a prescription drug from a formulary, unless the United States food and  
426 drug administration has issued a statement about the drug that calls into question the clinical  
427 safety of the drug, or the manufacturer of the drug has notified the United States food and drug  
428 administration of a manufacturing discontinuance or potential discontinuance of the drug as  
429 required by section 506C of the Federal Food, Drug, and Cosmetic Act, as codified in 21 U.S.C.  
430 §356c.

431 3. Coverage exemption determination process.

432 a. To ensure continuity of care, a health carrier, health plan, or utilization review  
433 organization shall provide a covered person and prescribing health care professional with access  
434 to a clear and convenient process to request a coverage exemption determination. A health  
435 carrier, health plan, or utilization review organization may use its existing medical exceptions

436 process to satisfy this requirement. The process used shall be easily accessible on the internet site  
437 of the health carrier, health benefit plan, or utilization review organization.

438         b. A health carrier, health benefit plan, or utilization review organization shall respond to  
439 a coverage exemption determination request within seventy-two hours of receipt. In cases where  
440 exigent circumstances exist, a health carrier, health benefit plan, or utilization review  
441 organization shall respond within twenty-four hours of receipt. If a response by a health carrier,  
442 health benefit plan, or utilization review organization is not received within the applicable time  
443 period, the coverage exemption shall be deemed granted.

444         (1) A coverage exemption shall be expeditiously granted for a discontinued health  
445 benefit plan if a covered person enrolls in a comparable plan offered by the same health carrier,  
446 and all of the following conditions apply:

447             (a) The covered person is medically stable on a prescription drug as determined by the  
448 prescribing health care professional.

449             (b) The prescribing health care professional continues to prescribe the drug for the  
450 covered person for the medical condition.

451             (c) In comparison to the discontinued health benefit plan, the new health benefit plan  
452 does any of the following:

453                 (i) Limits or reduces the maximum coverage of prescription drug benefits.

454                 (ii) Increases cost sharing for the prescription drug.

455                 (iii) Moves the prescription drug to a more restrictive tier if the health carrier uses a  
456 formulary with tiers.



457 (iv) Excludes the prescription drug from the formulary.

458 c. Upon granting of a coverage exemption for a drug prescribed by a covered person's  
459 prescribing health care professional, a health carrier, health benefit plan, or utilization review  
460 organization shall authorize coverage no more restrictive than that offered in a discontinued  
461 health benefit plan, or than that offered prior to implementation of restrictive changes to the  
462 health benefit plan's formulary after the current plan year began.

463 d. If a determination is made to deny a request for a coverage exemption, the health  
464 carrier, health benefit plan, or utilization review organization shall provide the covered person or  
465 the covered person's authorized representative and the authorized person's prescribing health  
466 care professional with the reason for denial and information regarding the procedure to appeal  
467 the denial. Any determination to deny a coverage exemption may be appealed by a covered  
468 person or the covered person's authorized representative.

469 e. A health carrier, health benefit plan, or utilization review organization shall uphold or  
470 reverse a determination to deny a coverage exemption within seventy-two hours of receipt of an  
471 appeal of denial. In cases where exigent circumstances exist, a health carrier, health benefit plan,  
472 or utilization review organization shall uphold or reverse a determination to deny a coverage  
473 exemption within twenty-four hours of receipt. If the determination to deny a coverage  
474 exemption is not upheld or reversed on appeal within the applicable time period, the denial shall  
475 be deemed reversed and the coverage exemption shall be deemed approved.

476 f. If a determination to deny a coverage exemption is upheld on appeal, the health  
477 carrier, health benefit plan, or utilization review organization shall provide the covered person or  
478 covered person's authorized representative and the covered person's prescribing health care

479 professional with the reason for upholding the denial on appeal and information regarding the  
480 procedure to request external review of the denial pursuant to chapter 514J. Any denial of a  
481 request for a coverage exemption that is upheld on appeal shall be considered a final adverse  
482 determination for purposes of chapter 514J and is eligible for a request for external review by a  
483 covered person or the covered person's authorized representative pursuant to chapter 514J.

484 4. Limitations. This section shall not be construed to do any of the following:

485 a. Prevent a health care professional from prescribing another drug covered by the health  
486 carrier that the health care professional deems medically necessary for the covered person.

487 b. Prevent a health carrier from doing any of the following:

488 (1) Adding a prescription drug to its formulary.

489 (2) Removing a prescription drug from its formulary if the drug manufacturer has  
490 removed the drug for sale in the United States.

491 (3) Requiring a pharmacist to effect a substitution of a generic or interchangeable  
492 biological drug product pursuant to section 12EE of Chapter 112.

493 5. Enforcement. The commissioner may take any enforcement action under the  
494 commissioner's authority to enforce compliance with this section.

495 6. Applicability. This section is applicable to a health benefit plan that is delivered,  
496 issued for delivery, continued, or renewed in this state on or after January 1, 2019.