

HOUSE No. 1237

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: | DATE ADDED: |
|------------------------------|-----------------------|------------------|
| <i>Michael S. Day</i> | <i>31st Middlesex</i> | <i>1/28/2021</i> |
| <i>Lindsay N. Sabadosa</i> | <i>1st Hampshire</i> | <i>2/26/2021</i> |
| <i>Christopher Hendricks</i> | <i>11th Bristol</i> | <i>2/26/2021</i> |

HOUSE No. 1237

By Mr. Day of Stoneham, a petition (accompanied by bill, House, No. 1237) of Michael S. Day, Lindsay N. Sabadosa and Christopher Hendricks relative to changes to health benefit plans that cause certain covered persons to switch to less costly alternate prescription drugs. Financial Services.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. 949 OF 2019-2020.]

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-Second General Court
(2021-2022)**

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, 2022.

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, 2022.

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, 2022.

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, 2022.