

Senate File 178 - Introduced

SENATE FILE 178

BY CARLIN

A BILL FOR

1 An Act relating to continuity of care and nonmedical switching
2 by health carriers, health benefit plans, and utilization
3 review organizations, and including applicability
4 provisions.

5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 514F.8 Continuity of care —
2 nonmedical switching.

3 1. *Definitions.* For the purpose of this section:

4 a. "*Authorized representative*" means the same as defined in
5 section 514J.102.

6 b. "*Commissioner*" means the commissioner of insurance.

7 c. "*Cost sharing*" means any coverage limit, copayment,
8 coinsurance, deductible, or other out-of-pocket expense
9 requirement.

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

14 e. "*Coverage exemption determination*" means a determination
15 made by a health carrier, health benefit plan, or utilization
16 review organization whether to cover a prescription drug that
17 is otherwise excluded from coverage.

18 f. "*Covered person*" means the same as defined in section
19 514J.102.

20 g. "*Demonstrated bioavailability*" means the same as defined
21 in section 155A.3.

22 h. "*Discontinued health benefit plan*" means a covered
23 person's existing health benefit plan that is discontinued by a
24 health carrier during open enrollment for the next plan year.

25 i. "*Formulary*" means a complete list of prescription drugs
26 eligible for coverage under a health benefit plan.

27 j. "*Generic name*" means the same as defined in section
28 155A.3.

29 k. "*Health benefit plan*" means the same as defined in
30 section 514J.102.

31 l. "*Health care professional*" means the same as defined in
32 section 514J.102.

33 m. "*Health care services*" means the same as defined in
34 section 514J.102.

35 n. "*Health carrier*" means the same as defined in section

1 514J.102.

2 *o.* "Interchangeable biological product" means the same as
3 defined in section 155A.3.

4 *p.* "Nonmedical switching" means a health benefit plan's
5 restrictive changes to the health benefit plan's formulary
6 after the current plan year has begun or during the open
7 enrollment period for the upcoming plan year, causing a covered
8 person who is medically stable on the covered person's current
9 prescribed drug as determined by the prescribing health care
10 professional, to switch to a less costly alternate prescription
11 drug.

12 *q.* "Open enrollment" means the yearly time period during
13 which an individual can enroll in a health benefit plan.

14 *r.* "Utilization review" means the same as defined in 514F.7.

15 *s.* "Utilization review organization" means the same as
16 defined in 514F.7.

17 2. *Nonmedical switching.* With respect to a health carrier
18 that has entered into a health benefit plan with a covered
19 person that covers prescription drug benefits, all of the
20 following apply:

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

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

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

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

33 *b.* Coverage of a covered person's prescription drug, as
34 described in paragraph "a", shall continue through the last day
35 of the covered person's eligibility under the health benefit

1 plan, inclusive of any open enrollment period.

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

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

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

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

10 (4) Removing a prescription drug from a formulary, unless
11 the United States food and drug administration has issued a
12 statement about the drug that calls into question the clinical
13 safety of the drug, or the manufacturer of the drug has
14 notified the United States food and drug administration of a
15 manufacturing discontinuance or potential discontinuance of the
16 drug as required by section 506C of the Federal Food, Drug, and
17 Cosmetic Act, as codified in 21 U.S.C. §356c.

18 *d.* A drug product with the same generic name and
19 demonstrated bioavailability, or an interchangeable biological
20 product, shall be considered equivalent to the prescription
21 drug prescribed by the covered person's health care
22 professional.

23 3. *Coverage exemption determination process.*

24 *a.* To ensure continuity of care, a health carrier, health
25 plan, or utilization review organization shall provide a
26 covered person and prescribing health care professional
27 with access to a clear and convenient process to request a
28 coverage exemption determination. A health carrier, health
29 plan, or utilization review organization may use its existing
30 medical exceptions process to satisfy this requirement. The
31 process shall be easily accessible on the internet site of the
32 health carrier, health benefit plan, or utilization review
33 organization.

34 *b.* A health carrier, health benefit plan, or utilization
35 review organization shall respond to a coverage exemption

1 determination request within seventy-two hours of receipt. In
2 cases where exigent circumstances exist, the health carrier,
3 health benefit plan, or utilization review organization shall
4 respond within twenty-four hours of receipt. If a response by
5 the health carrier, health benefit plan, or utilization review
6 organization is not received within the applicable time period,
7 the coverage exemption shall be deemed granted.

8 *c.* A coverage exemption shall be expeditiously granted for a
9 discontinued health benefit plan if a covered person enrolls in
10 a comparable plan offered by the same health carrier, and all
11 of the following conditions apply:

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

14 (2) The prescribing health care professional continues
15 to prescribe the drug for the covered person for the covered
16 person's medical condition.

17 (3) In comparison to the discontinued health benefit plan,
18 the new health benefit plan does any of the following:

19 (a) Limits or reduces the maximum coverage of prescription
20 drug benefits.

21 (b) Increases cost sharing for the prescription drug.

22 (c) Moves the prescription drug to a more restrictive tier
23 if the health carrier uses a formulary with tiers.

24 (d) Excludes the prescription drug from the health benefit
25 plan's formulary.

26 *d.* Upon granting of a coverage exemption for a drug
27 prescribed by a covered person's prescribing health care
28 professional, a health carrier, health benefit plan, or
29 utilization review organization shall authorize coverage no
30 more restrictive than that offered in a discontinued health
31 benefit plan, or than that offered prior to implementation of
32 restrictive changes to the health benefit plan's formulary
33 after the current plan year began.

34 *e.* If a determination is made to deny a request for a
35 coverage exemption, the health carrier, health benefit plan,

1 or utilization review organization shall provide the covered
2 person or the covered person's authorized representative and
3 the authorized person's prescribing health care professional
4 with the reason for denial and information regarding the
5 procedure to appeal the denial. Any determination to deny a
6 coverage exemption may be appealed by a covered person or the
7 covered person's authorized representative.

8 *f.* A health carrier, health benefit plan, or utilization
9 review organization shall uphold or reverse a determination to
10 deny a coverage exemption within seventy-two hours of receipt
11 of an appeal of denial. In cases where exigent circumstances
12 exist, a health carrier, health benefit plan, or utilization
13 review organization shall uphold or reverse a determination to
14 deny a coverage exemption within twenty-four hours of receipt.
15 If the determination to deny a coverage exemption is not upheld
16 or reversed on appeal within the applicable time period, the
17 denial shall be deemed reversed and the coverage exemption
18 shall be deemed approved.

19 *g.* If a determination to deny a coverage exemption is
20 upheld on appeal, the health carrier, health benefit plan,
21 or utilization review organization shall provide the covered
22 person or the covered person's authorized representative and
23 the covered person's prescribing health care professional with
24 the reason for upholding the denial on appeal and information
25 regarding the procedure to request external review of the
26 denial pursuant to chapter 514J. Any denial of a request for a
27 coverage exemption that is upheld on appeal shall be considered
28 a final adverse determination for purposes of chapter 514J and
29 is eligible for a request for external review by a covered
30 person or the covered person's authorized representative
31 pursuant to chapter 514J.

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

34 *a.* Prevent a health care professional from prescribing
35 another drug covered by the health carrier that the health care

1 professional deems medically necessary for the covered person.

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

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

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

7 5. *Enforcement.* The commissioner may take any enforcement
8 action under the commissioner's authority to enforce compliance
9 with this section.

10 Sec. 2. APPLICABILITY. This Act applies to a health benefit
11 plan that is delivered, issued for delivery, continued, or
12 renewed in this state on or after January 1, 2022.

13 EXPLANATION

14 The inclusion of this explanation does not constitute agreement with
15 the explanation's substance by the members of the general assembly.

16 This bill relates to the continuity of care for a covered
17 person and nonmedical switching by health carriers, health
18 benefit plans, and utilization review organizations.

19 The bill defines "nonmedical switching" as a health benefit
20 plan's restrictive changes to the health benefit plan's
21 formulary after the current plan year has begun or during the
22 open enrollment period for the upcoming plan year, causing a
23 covered person who is medically stable on the covered person's
24 current prescribed drug as determined by the prescribing
25 health care professional, to switch to a less costly alternate
26 prescription drug.

27 The bill provides that during a covered person's eligibility
28 under a health benefit plan, inclusive of any open enrollment
29 period, a health plan carrier, health benefit plan, or
30 utilization review organization shall not limit or exclude
31 coverage of a prescription drug for the covered person if the
32 covered person is medically stable on the drug as determined
33 by the prescribing health care professional, the drug was
34 previously approved by the health carrier for coverage for
35 the person, and the covered person's prescribing health care

1 professional has prescribed the drug for the person's medical
2 condition within the previous six months. The bill includes,
3 as prohibited limitations or exclusions, reducing the maximum
4 coverage of prescription drug benefits, increasing cost sharing
5 for a covered drug, moving a drug to a more restrictive tier,
6 and removing a drug from a formulary. A prescription drug
7 may, however, be removed from a formulary if the United States
8 food and drug administration issues a statement regarding the
9 clinical safety of the drug, or the manufacturer of the drug
10 notifies the United States food and drug administration of a
11 manufacturing discontinuance or potential discontinuance of the
12 drug as required by section 506c of the Federal Food, Drug,
13 and Cosmetic Act. The bill provides that a drug product with
14 the same generic name and demonstrated bioavailability, or an
15 interchangeable biological product, is considered equivalent to
16 the prescription drug prescribed by the covered person's health
17 care professional.

18 The bill requires a covered person and prescribing health
19 care professional to have access to a process to request a
20 coverage exemption determination. The bill defines "coverage
21 exemption determination" as a determination made by a
22 health carrier, health benefit plan, or utilization review
23 organization whether to cover a prescription drug that is
24 otherwise excluded from coverage.

25 A coverage exemption determination request must be approved
26 or denied by the health carrier, health benefit plan, or
27 utilization review organization within 72 hours, or within 24
28 hours if exigent circumstances exist. If a determination is
29 not received within the applicable time period the coverage
30 exemption is deemed granted.

31 The bill requires a coverage exemption to be expeditiously
32 granted for a health benefit plan that is discontinued for the
33 next plan year if a covered person enrolls in a comparable
34 plan offered by the same health carrier, and in comparison
35 to the discontinued health benefit plan, the new health

1 benefit plan limits or reduces the maximum coverage for a
2 prescription drug, increases cost sharing for the prescription
3 drug, moves the prescription drug to a more restrictive
4 tier, or excludes the prescription drug from the formulary.
5 If a coverage exemption is granted, the bill requires an
6 authorization of coverage that is no more restrictive than
7 that offered in the discontinued health benefit plan, or than
8 that offered prior to implementation of restrictive changes
9 to the health benefit plan's formulary after the current plan
10 year began. If a determination is made to deny a request for
11 a coverage exemption, the reason for denial and the procedure
12 to appeal the denial must be provided to the requestor. Any
13 determination to deny a coverage exemption may be appealed to
14 the health carrier, health benefit plan, or utilization review
15 organization. A determination to uphold or reverse denial of
16 a coverage exemption must be made within 72 hours of receipt
17 of an appeal, or within 24 hours if exigent circumstances
18 exist. If a determination is not made within the applicable
19 time period, the denial is deemed reversed and the coverage
20 exemption is deemed approved.

21 If a determination to deny a coverage exemption is upheld on
22 appeal, the reason for upholding the denial and the procedure
23 to request external review of the denial pursuant to Code
24 chapter 514J must be provided to the individual who filed the
25 appeal. Any denial of a request for a coverage exemption that
26 is upheld on appeal is considered a final adverse determination
27 for purposes of Code chapter 514J and is eligible for a request
28 for external review by a covered person or the covered person's
29 authorized representative pursuant to Code chapter 514J.

30 The bill shall not be construed to prevent a health care
31 professional from prescribing another drug covered by the
32 health carrier that the health care professional deems
33 medically necessary for the covered person.

34 The bill shall not be construed to prevent a health carrier
35 from adding a drug to its formulary or from removing a drug

1 from its formulary if the drug manufacturer removes the drug
2 for sale in the United States.

3 The bill allows the commissioner to take any necessary
4 enforcement action under the commissioner's authority to
5 enforce compliance with the bill.

6 The bill is applicable to health benefit plans that are
7 delivered, issued for delivery, continued, or renewed in this
8 state on or after January 1, 2022.