HOUSE FILE 2089
BY MOORE

A BILL FOR

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

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

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

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

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

b. "Commissioner" means the commissioner of insurance.

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

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

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

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

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

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

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

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

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

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

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

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

514J.102.

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

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

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

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

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

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

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

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

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

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

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

plan, inclusive of any open enrollment period.

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

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

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

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

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

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

3. *Coverage exemption determination process.*

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

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

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

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

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

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

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

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

(b) Increases cost sharing for the prescription drug.

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

(d) Excludes the prescription drug from the formulary.

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

e. If a determination is made to deny a request for a coverage exemption, the health carrier, health benefit plan, or utilization review organization shall provide the covered

person or the covered person's authorized representative and the authorized person's prescribing health care professional with the reason for denial and information regarding the procedure to appeal the denial. Any determination to deny a coverage exemption may be appealed by a covered person or the covered person's authorized representative.

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

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

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

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

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

(1) Adding a prescription drug to its formulary.

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

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

Sec. 2. APPLICABILITY. This Act applies to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2021.

EXPLANATION

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

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

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

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

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

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

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

The bill requires a coverage exemption to be expeditiously granted for a health benefit plan discontinued for the next plan year if a covered person enrolls in a comparable plan offered by the same health carrier, and in comparison to the discontinued health benefit plan, the new health benefit plan limits or reduces the maximum coverage for a prescription drug,

increases cost sharing for the prescription drug, moves the prescription drug to a more restrictive tier, or excludes the prescription drug from the formulary.

If a coverage exemption is granted, the bill requires an authorization of coverage that is no more restrictive than that offered in a discontinued health benefit plan, or than that offered prior to implementation of restrictive changes to the health benefit plan's formulary after the current plan year began.

If a determination is made to deny a request for a coverage exemption, the reason for denial and the procedure to appeal the denial must be provided to the requestor. Any determination to deny a coverage exemption may be appealed to the health carrier, health benefit plan, or utilization review organization.

A determination to uphold or reverse denial of a coverage exemption must be made within 72 hours of receipt of an appeal, or within 24 hours if exigent circumstances exist. If a determination is not made within the applicable time period, the denial is deemed reversed and the coverage exemption is deemed approved.

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

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

The bill shall not be construed to prevent a health carrier

from adding a drug to its formulary or removing a drug from its formulary if the drug manufacturer removes the drug for sale in the United States.

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

The bill is applicable to health benefit plans that are delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2021.