HOUSE . . . . . No. 4491

The Commonwealth of Massachusetts

HOUSE OF REPRESENTATIVES, September 18, 2025.

The committee on Financial Services, to whom was referred the petition (accompanied by bill, House, No. 1125) of Michael S. Day relative to changes to health benefit plans that cause certain covered persons to switch to less costly alternate prescription drugs, reports recommending that the accompanying bill (House, No. 4491) ought to pass.

For the committee,

JAMES M. MURPHY.

FILED ON: 9/8/2025

HOUSE . . . . . No. 4491

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

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:

Section 1. Chapter 175 of the General Laws is hereby amended by inserting after section 230 the following section:-

Section 231.

1. Definitions. For the purpose of this section:

a. "Commissioner" means the commissioner of insurance.

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

c. "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.

d. “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.

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

f. “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.

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

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

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

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

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

l. “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, inclusive of changes to the drug dosage, as determined by the prescribing health care professional, to switch to a less costly alternate prescription drug.

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

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

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

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.

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.

(1) 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:

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

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

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

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

(ii) Increases cost sharing for the prescription drug.

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

(iv) Excludes the prescription drug from the formulary.

c. 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.

d. 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.

e. 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.

f. 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.

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

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

6. Applicability. This section is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2026.

Section 2. Chapter 176A of the General Laws is hereby amended by inserting after section 38 the following section:-

Section 39.

1. Definitions. For the purpose of this section:

a. "Commissioner" means the commissioner of insurance.

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

c. “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.

d. “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.

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

f. “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.

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

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

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

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

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

l. “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, inclusive of changes to the drug dosage, as determined by the prescribing health care professional, to switch to a less costly alternate prescription drug.

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

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

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

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.

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.

(1) 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:

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

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

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

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

(ii) Increases cost sharing for the prescription drug.

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

(iv) Excludes the prescription drug from the formulary.

c. 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.

d. 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.

e. 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.

f. 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.

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

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

6. Applicability. This section is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2026.

Section 3. Chapter 176B of the General Laws is hereby amended by inserting after section 25 the following section:-

Section 26.

1. Definitions. For the purpose of this section:

a. “Commissioner” means the commissioner of insurance.

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

c. “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.

d. “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.

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

f. “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.

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

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

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

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

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

l. “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, inclusive of changes to the drug dosage, as determined by the prescribing health care professional, to switch to a less costly alternate prescription drug.

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

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

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

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.

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.

(1) 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:

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

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

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

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

(ii) Increases cost sharing for the prescription drug.

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

(iv) Excludes the prescription drug from the formulary.

c. 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.

d. 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.

e. 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.

f. 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.

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

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

6. Applicability. This section is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2026.

Section 4. Chapter 176G of the General Laws is hereby amended by inserting after section 33 the following section:-

Section 34.

1. Definitions. For the purpose of this section:

a. "Commissioner" means the commissioner of insurance.

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

c. "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.

d. "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.

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

f. "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.

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

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

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

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

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

l. “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, inclusive of changes to the drug dosage, as determined by the prescribing health care professional, to switch to a less costly alternate prescription drug.

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

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

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

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.

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.

(1) 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:

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

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

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

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

(ii) Increases cost sharing for the prescription drug.

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

(iv) Excludes the prescription drug from the formulary.

c. 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.

d. 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.

e. 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.

f. 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.

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

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

6. Applicability. This section is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2026.