SENATE BILL No. 585

DIGEST OF INTRODUCED BILL

Citations Affected: IC 5-10-8; IC 12-7-2; IC 12-15-35.5; IC 27-8-5; IC 27-13-38.

Synopsis: Continuous prescription drug coverage. Prohibits state employee health plans, Medicaid programs, accident and sickness insurers, and health maintenance organizations from changing coverage of a prescribed drug during the continuous enrollment of a covered individual, recipient, or enrollee. Specifies requirements for coverage exception requests and discontinuation of certain coverage.

Effective: July 1, 2019.

Brown L

January 14, 2019, read first time and referred to Committee on Health and Provider Services.

Introduced

First Regular Session of the 121st General Assembly (2019)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2018 Regular and Special Session of the General Assembly.

SENATE BILL No. 585

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-18, AS ADDED BY P.L.19-2016, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 18. (a) The definitions in section 17 of this chapter apply throughout this section.

(b) This section applies to a state employee health plan that uses a formulary, cost sharing, or utilization review for prescription drug coverage. **However, to the extent that this section conflicts with section 21 of this chapter, section 21 of this chapter is controlling.**

(c) A state employee health plan shall not remove a prescription drug from the state employee health plan's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review requirements that apply to a prescription drug unless the state employee health plan does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each covered individual for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time a covered individual for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the covered individual:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.

SECTION 2. IC 5-10-8-21 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 21. (a) As used in this section, "continuous enrollment" or "continuously enrolled" means enrollment in one (1) or more state employee health plans with no gap in coverage.**

(b) As used in this section, "coverage exception" means an exception:

(1) to a state employee health plan's limitation or exclusion of coverage for a drug; and

(2) under which coverage for the drug is provided under the state employee health plan.

(c) As used in this section, "covered individual" means an individual who is entitled to coverage under a state employee health plan.

(d) As used in this section, "drug" means a prescription drug.

(e) As used in this section, "formulary" means a complete list of drugs eligible for coverage under a state employee health plan's benefits.

(f) As used in this section, "limitation or exclusion of coverage" means the following:

(1) Exclusion of coverage for a drug under a state employee health plan.

(2) Limitation or reduction of the maximum drug benefit under a state employee health plan.

(3) Increase of the out-of-pocket costs applicable to a drug under a state employee health plan.

(4) Movement of a drug to a more restrictive coverage category or tier under the state employee health plan.

(5) Removal of a drug from a state employee health plan's formulary, unless the:

(A) federal Food and Drug Administration has issued a statement calling into question the clinical safety of the drug; or

(B) manufacturer of the drug has notified the federal Food and Drug Administration of a manufacturing

discontinuance, or potential discontinuance, of the drug as required by 21 U.S.C. 356c.

(6) Discontinuation of coverage of a drug before the day on which a covered individual is no longer continuously enrolled in a state employee health plan.

(g) As used in this section, "state employee health plan" refers to the following that provide coverage for drugs:

(1) A self-insurance program established under section 7(b) of this chapter to provide group health coverage.

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

The term includes a person that administers drug benefits on behalf of a state employee health plan.

(h) A state employee health plan shall not impose a limitation or exclusion of coverage for a drug:

(1) that is currently prescribed for a continuously enrolled covered individual; and

(2) for which coverage has been provided for the covered individual for the same medical condition under any state employee health plan during the covered individual's continuous enrollment.

(i) A state employee health plan shall provide a clear, accessible, and convenient coverage exception process through which a covered individual and prescribing health provider may request a coverage exception.

(j) A state employee health plan shall respond to a request for a coverage exception, or an appeal of a coverage exception determination, not later than:

(1) seventy-two (72) hours; or

(2) if the request is urgent, twenty-four (24) hours;

after the state employee health plan receives the request. If the state employee health plan does not respond within the applicable period specified in this subsection, the request is considered to have been granted.

(k) If:

(1) a state employee health plan is discontinued during open enrollment;

(2) a covered individual under the state employee health plan described in subdivision (1) enrolls in a comparable state employee health plan;

(3) the covered individual's prescribing health provider continues to prescribe a drug described in subsection (h) for

the covered individual for the same medical condition; and

(4) in comparison with the discontinued state employee health plan, the enrollment in the comparable state employee health plan has the effect of a limitation or exclusion of coverage described in subsection (f)(2) through (f)(5);

the comparable state employee health plan shall grant a coverage exception for the drug.

(l) If a coverage exception is granted or considered to have been granted, the state employee health plan shall provide coverage that is not more restrictive than the coverage provided for the prescribed drug under the discontinued state employee health plan.

(m) This section does not do any of the following:

(1) Prevent a health provider from prescribing a drug for a covered individual if the health provider considers the drug to be medically appropriate to treat the covered individual.

(2) Prevent a pharmacist from substituting:

(A) generic drugs in accordance with IC 16-42-22; or

(B) biosimilar biological products in accordance with IC 16-42-25.

(3) Prevent a state employee health plan from:

(A) adding a drug to the state employee health plan's formulary; or

(B) removing a drug from the state employee health plan's formulary if the drug manufacturer has removed the drug from sale in the United States.

SECTION 3. IC 12-7-2-40.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 40.8. "Continuous enrollment" or "continuously enrolled", for purposes of IC 12-15-35.5-10, has the meaning set forth in IC 12-15-35.5-10.**

SECTION 4. IC 12-7-2-47.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 47.1. "Coverage exception", for purposes of IC 12-15-35.5-10, has the meaning set forth in IC 12-15-35.5-10.**

SECTION 5. IC 12-7-2-71 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 71. **(a) "Drug", for purposes of IC 12-15-35.5-10, means a prescription drug.**

(b) "Drug", for purposes of IC 12-23, means a drug or a controlled substance (as defined in IC 35-48-1).

SECTION 6. IC 12-7-2-88.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 88.4. "Formulary", for purposes of IC 12-15-35.5-10,**

has the meaning set forth in IC 12-15-35.5-10.

SECTION 7. IC 12-7-2-146, AS AMENDED BY P.L.130-2018, SECTION 42, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 146. "Program" refers to the following:

(1) For purposes of IC 12-10-7, the adult guardianship services program established by IC 12-10-7-5.

(2) For purposes of IC 12-10-10, the meaning set forth in IC 12-10-10-5.

(3) For purposes of IC 12-15-35.5-10, the meaning set forth in IC 12-15-35.5-10.

~~(3)~~ **(4)** For purposes of IC 12-17.2-2-14.2, the meaning set forth in IC 12-17.2-2-14.2(a).

~~(4)~~ **(5)** For purposes of IC 12-17.6, the meaning set forth in IC 12-17.6-1-5.

SECTION 8. IC 12-7-2-158, AS AMENDED BY P.L.145-2006, SECTION 59, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 158. "Recipient" means the following:

(1) For purposes of the following statutes, a person who has received or is receiving assistance for the person or another person under any of the following statutes:

(A) IC 12-10-6.

(B) IC 12-13.

(C) IC 12-14.

(D) IC 12-15.

(E) IC 12-17.6.

~~(E)~~ **(F)** IC 12-19.

(2) For purposes of IC 12-20-10 and IC 12-20-11:

(A) a single individual receiving township assistance; or

(B) if township assistance is received by a household with at least two (2) individuals, the member of the household most suited to perform available work.

SECTION 9. IC 12-15-35.5-7, AS AMENDED BY P.L.210-2015, SECTION 51, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 7. (a) Subject to subsections (b) and (c) **and section 10 of this chapter,** the office may place limits on quantities dispensed or the frequency of refills for any covered drug as required by law or for the purpose of:

(1) preventing fraud, abuse, or waste;

(2) preventing overutilization, inappropriate utilization, or inappropriate prescription practices that are contrary to:

(A) clinical quality and patient safety; and

(B) accepted clinical practice for the diagnosis and treatment

of mental illness and the considerations specified in subsection (h); or

(3) implementing a disease management program.

(b) Before implementing a limit described in subsection (a), the office shall:

(1) consider quality of care and the best interests of Medicaid recipients;

(2) seek the advice of the drug utilization review board, established by IC 12-15-35-19, at a public meeting of the board; and

(3) publish a provider bulletin that complies with the requirements of IC 12-15-13-6.

(c) Subject to subsection (d) **and section 10 of this chapter,** the board may establish and the office may implement a restriction on a drug described in section 3(b) of this chapter if:

(1) the board determines that data provided by the office indicates that a situation described in IC 12-15-35-28(a)(7)(A) through IC 12-15-35-28(a)(7)(K) requires an intervention to:

(A) prevent fraud, abuse, or waste;

(B) prevent overutilization, inappropriate utilization, or inappropriate prescription practices that are contrary to:

(i) clinical quality and patient safety; and

(ii) accepted clinical practice for the diagnosis and treatment of mental illness; or

(C) implement a disease management program; and

(2) the board approves and the office implements an educational intervention program for providers to address the situation.

(d) A restriction established under subsection (c) for any drug described in section 3(b) of this chapter:

(1) must comply with the procedures described in IC 12-15-35-35;

(2) may include requiring a recipient to be assigned to one (1) practitioner and one (1) pharmacy provider for purposes of receiving mental health medications;

(3) may not lessen the quality of care; and

(4) must be in the best interest of Medicaid recipients.

(e) Implementation of a restriction established under subsection (c) must provide for the dispensing of a temporary supply of the drug for a prescription not to exceed seven (7) business days, if additional time is required to review the request for override of the restriction. This subsection does not apply if the federal Food and Drug Administration has issued a boxed warning under 21 CFR 201.57(c)(1) that applies to

the drug and is applicable to the patient.

(f) Before implementing a restriction established under subsection (c), the office shall:

(1) seek the advice of the mental health Medicaid quality advisory committee established by IC 12-15-35-51; and

(2) publish a provider bulletin that complies with the requirements of IC 12-15-13-6.

(g) Subsections (c) through (f):

(1) apply only to drugs described in section 3(b) of this chapter; and

(2) do not apply to a restriction on a drug described in section 3(b) of this chapter that was approved by the board and implemented by the office before April 1, 2003.

(h) Restrictions referred to in subsection (c) to prevent overutilization, inappropriate utilization, or inappropriate prescription practices that are contrary to accepted clinical practices may include the implementation of the following:

(1) Encouraging dosages that enhance recipient adherence to a drug regimen.

(2) Encouraging monotherapy with limitations on the number of drugs from a specific drug class that a recipient may be taking at any one (1) time when there is no documentation of the severity and intensity of the target symptoms.

(3) Limiting the total number of scheduled psychiatric medications that a recipient may be taking at any one (1) time, when such limit is based on:

(A) established best practices; or

(B) guidelines implemented by the division of mental health and addiction for mental health state operated facilities.

(4) Encouraging, in accordance with IC 16-42-22-10, generic substitution when such a substitution would result in a net cost savings to the Medicaid program.

(i) Restrictions under subsection (h) may be overridden through the prior authorization review process in cases in which the prescriber demonstrates medical necessity for the prescribed medication.

SECTION 10. IC 12-15-35.5-10 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 10. (a) As used in this section, "continuous enrollment" or "continuously enrolled" means enrollment in one (1) or more programs with no gap in coverage.**

(b) As used in this section, "coverage exception" means an exception:

(1) to a program's limitation or exclusion of coverage for a drug; and

(2) under which coverage for the drug is provided under the program.

(c) As used in this section, "formulary" means a complete list of drugs eligible for coverage under a program.

(d) As used in this section, "limitation or exclusion of coverage" means the following:

(1) Exclusion of coverage for a drug under a program.

(2) Limitation or reduction of the maximum drug benefit under a program.

(3) Increase of the out-of-pocket costs applicable to a drug under a program.

(4) Movement of a drug to a more restrictive coverage category or tier under a program.

(5) Removal of a drug from a program's formulary, unless the:

(A) federal Food and Drug Administration has issued a statement calling into question the clinical safety of the drug; or

(B) manufacturer of the drug has notified the federal Food and Drug Administration of a manufacturing discontinuance, or potential discontinuance, of the drug as required by 21 U.S.C. 356c.

(6) Discontinuation of coverage of a drug before the day on which a recipient is no longer continuously enrolled in a program.

(e) As used in this section, "program" refers to a program described in section 1 of this chapter. The term includes a contractor that administers drug benefits on behalf of a program.

(f) A program shall not impose a limitation or exclusion of coverage for a drug:

(1) that is currently prescribed for a continuously enrolled recipient; and

(2) for which coverage has been provided for the recipient for the same medical condition under any program during the recipient's continuous enrollment.

(g) A program shall provide a clear, accessible, and convenient coverage exception process through which a recipient and prescribing health provider may request a coverage exception.

(h) A program shall respond to a request for a coverage exception, or an appeal of a coverage exception determination, not

later than:

(1) seventy-two (72) hours; or

(2) if the request is urgent, twenty-four (24) hours;

after the program receives the request. If the program does not respond within the applicable period specified in this subsection, the request is considered to have been granted.

(i) If:

(1) a program is discontinued during open enrollment;

(2) a recipient under the program described in subdivision (1) enrolls in a comparable program;

(3) the recipient's prescribing health provider continues to prescribe a drug described in subsection (f) for the recipient for the same medical condition; and

(4) in comparison with the discontinued program, the enrollment in the comparable program has the effect of a limitation or exclusion of coverage described in subsection (d)(2) through (d)(5);

the comparable program shall grant a coverage exception for the drug.

(j) If a coverage exception is granted or considered to have been granted, the program shall provide coverage that is not more restrictive than the coverage provided for the prescribed drug under the discontinued program.

(k) This section does not do any of the following:

(1) Prevent a health provider from prescribing a drug for a recipient if the health provider considers the drug to be medically appropriate to treat the recipient.

(2) Prevent a pharmacist from substituting:

(A) generic drugs in accordance with IC 16-42-22; or

(B) biosimilar biological products in accordance with IC 16-42-25.

(3) Prevent a program from:

(A) adding a drug to the program's formulary; or

(B) removing a drug from the program's formulary if the drug manufacturer has removed the drug from sale in the United States.

SECTION 11. IC 27-8-5-31, AS ADDED BY P.L.19-2016, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 31. (a) The definitions in section 30 of this chapter apply throughout this section.

(b) This section applies to an insurer that uses a formulary, cost sharing, or utilization review for prescription drug coverage. **However,**

to the extent that this section conflicts with section 32 of this chapter, section 32 of this chapter is controlling.

(c) An insurer shall not remove a prescription drug from the insurer's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review requirements that apply to a prescription drug unless the insurer does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each insured for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time an insured for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the insured:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.

SECTION 12. IC 27-8-5-32 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 32. (a) As used in this section, "accident and sickness insurance policy" means an insurance policy that provides one (1) or more of the types of insurance described in IC 27-1-5-1, Classes 1(b) and 2(a), and provides coverage for drugs. The term does not include the following:**

(1) Accident only, credit, dental, vision, Medicare supplement, long term care, or disability income insurance.

(2) Coverage issued as a supplement to liability insurance.

(3) Worker's compensation or similar insurance.

(4) Automobile medical payment insurance.

(5) A specified disease policy.

(6) A short term insurance plan that:

(A) may not be renewed; and

(B) has a duration of not more than six (6) months.

(7) A policy that provides indemnity benefits not based on any expense incurred requirement, including a plan that provides coverage for:

(A) hospital confinement, critical illness, or intensive care; or

(B) gaps for deductibles or copayments.

(8) A supplemental plan that always pays in addition to other coverage.

(9) A student health plan.

(10) An employer sponsored health benefit plan that is:

(A) provided to individuals who are eligible for Medicare; and

(B) not marketed as, or held out to be, a Medicare supplement policy.

(b) As used in this section, "continuous enrollment" or "continuously enrolled" means enrollment in one (1) or more accident and sickness insurance policies issued by the same insurer with no gap in coverage.

(c) As used in this section, "coverage exception" means an exception:

(1) to an accident and sickness insurance policy's exclusion of coverage for a drug; and

(2) under which coverage for the drug is provided under the accident and sickness insurance policy.

(d) As used in this section, "covered individual" means an individual who is entitled to coverage under an accident and sickness insurance policy.

(e) As used in this section, "drug" means a prescription drug.

(f) As used in this section, "formulary" means a complete list of drugs eligible for coverage under an accident and sickness insurance policy's benefits.

(g) As used in this section, "insurer" means an insurer that issues an accident and sickness insurance policy. The term includes a person that administers drug benefits under an accident and sickness insurance policy.

(h) As used in this section, "limitation or exclusion of coverage" means the following:

(1) Exclusion of coverage for a drug under an accident and sickness insurance policy.

(2) Limitation or reduction of the maximum drug benefit under an accident and sickness insurance policy.

(3) Increase of the out-of-pocket costs applicable to a drug under an accident and sickness insurance policy.

(4) Movement of a drug to a more restrictive coverage category or tier under an accident and sickness insurance policy.

(5) Removal of a drug from an accident and sickness insurance policy's formulary, unless the:

(A) federal Food and Drug Administration has issued a statement calling into question the clinical safety of the drug; or

(B) manufacturer of the drug has notified the federal Food and Drug Administration of a manufacturing discontinuance, or potential discontinuance, of the drug as required by 21 U.S.C. 356c.

(6) Discontinuation of coverage of a drug before the day on which a covered individual is no longer continuously enrolled in an accident and sickness insurance policy.

(i) An insurer shall not impose a limitation or exclusion of coverage for a drug:

(1) that is currently prescribed for a continuously enrolled covered individual; and

(2) for which coverage has been provided for the covered individual for the same medical condition under any accident and sickness insurance policy during the covered individual's continuous enrollment.

(j) An insurer shall provide a clear, accessible, and convenient coverage exception process through which a covered individual and prescribing health provider may request a coverage exception.

(k) An insurer shall respond to a request for a coverage exception, or an appeal of a coverage exception determination, not later than:

(1) seventy-two (72) hours; or

(2) if the request is urgent, twenty-four (24) hours;

after the insurer receives the request. If the insurer does not respond within the applicable period specified in this subsection, the request is considered to have been granted.

(l) If:

(1) an accident and sickness insurance policy is discontinued during open enrollment;

(2) a covered individual under the accident and sickness insurance policy described in subdivision (1) enrolls in a comparable accident and sickness insurance policy issued by the same insurer as the discontinued accident and sickness insurance policy;

(3) the covered individual's prescribing health provider continues to prescribe a drug described in subsection (i) for the covered individual for the same medical condition; and

(4) in comparison with the discontinued accident and sickness insurance policy, the enrollment in the comparable accident and sickness insurance policy has the effect of a limitation or exclusion of coverage described in subsection (h)(2) through (h)(5);

the insurer shall grant a coverage exception for the drug under the comparable accident and sickness insurance policy.

(m) If a coverage exception is granted or considered to have been granted, the insurer shall provide coverage under the comparable accident and sickness insurance policy that is not more restrictive than the coverage provided for the prescribed drug under the discontinued accident and sickness insurance policy.

(n) This section does not do any of the following:

(1) Prevent a health provider from prescribing a drug for a covered individual if the health provider considers the drug to be medically appropriate to treat the covered individual.

(2) Prevent a pharmacist from substituting:

(A) generic drugs in accordance with IC 16-42-22; or

(B) biosimilar biological products in accordance with IC 16-42-25.

(3) Prevent an insurer from:

(A) adding a drug to an accident and sickness insurance policy's formulary; or

(B) removing a drug from an accident and sickness insurance policy's formulary if the drug manufacturer has removed the drug from sale in the United States.

(o) A violation of this section by an insurer is an unfair and deceptive act or practice in the business of insurance under IC 27-4-1-4.

SECTION 13. IC 27-13-38-7, AS ADDED BY P.L.19-2016, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 7. (a) The definitions in IC 27-13-7-23 apply throughout this section.

(b) A health maintenance organization shall not remove a prescription drug from the health maintenance organization's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review program requirements that apply to a prescription drug unless that health maintenance organization does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each enrollee for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time an enrollee for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the enrollee:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.

(c) To the extent that this section conflicts with section 9 of this chapter, section 9 of this chapter is controlling.

SECTION 14. IC 27-13-38-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: **Sec. 9. (a) As used in this section, "continuous enrollment" or "continuously enrolled" means enrollment in one (1) or more individual contracts or group contracts entered into by the same health maintenance organization with no gap in coverage.**

(b) As used in this section, "coverage exception" means an exception:

(1) to an individual contract's or a group contract's exclusion of coverage for a drug; and

(2) under which coverage for the drug is provided under the individual contract or group contract.

(c) As used in this section, "drug" means a prescription drug.

(d) As used in this section, "formulary" means a complete list of drugs eligible for coverage under an individual contract's, or a group contract's, benefits.

(e) As used in this section, "group contract" means a group contract that provides drug benefits.

(f) As used in this section, "health maintenance organization" includes a person that administers drug benefits under an individual contract or a group contract.

(g) As used in this section, "individual contract" means an individual contract that provides drug benefits.

(h) As used in this section, "limitation or exclusion of coverage" means the following:

(1) Exclusion of coverage for a drug under an individual contract or a group contract.

(2) Limitation or reduction of the maximum drug benefit under an individual contract or a group contract.

(3) Increase of the out-of-pocket costs applicable to a drug under an individual contract or a group contract.

(4) Movement of a drug to a more restrictive coverage category or tier under an individual contract or a group contract.

(5) Removal of a drug from an individual contract's or a group contract's formulary, unless the:

(A) federal Food and Drug Administration has issued a

statement calling into question the clinical safety of the drug; or

(B) manufacturer of the drug has notified the federal Food and Drug Administration of a manufacturing discontinuance, or potential discontinuance, of the drug as required by 21 U.S.C. 356c.

(6) Discontinuation of coverage of a drug before the day on which an enrollee is no longer continuously enrolled in an individual contract or a group contract.

(i) A health maintenance organization shall not impose a limitation or exclusion of coverage for a drug:

(1) that is currently prescribed for a continuously enrolled enrollee; and

(2) for which coverage has been provided for the enrollee for the same medical condition under any individual contract or group contract during the enrollee's continuous enrollment.

(j) A health maintenance organization shall provide a clear, accessible, and convenient coverage exception process through which an enrollee and a prescribing health provider may request a coverage exception.

(k) A health maintenance organization shall respond to a request for a coverage exception, or an appeal of a coverage exception determination, not later than:

(1) seventy-two (72) hours; or

(2) if the request is urgent, twenty-four (24) hours;

after the health maintenance organization receives the request. If the health maintenance organization does not respond within the applicable period specified in this subsection, the request is considered to have been granted.

(l) If:

(1) an individual contract, or a group contract, is discontinued during open enrollment;

(2) an enrollee under the individual contract or group contract described in subdivision (1) enrolls in a comparable individual contract or group contract entered into by the same health maintenance organization as the discontinued individual contract or group contract;

(3) the enrollee's prescribing health provider continues to prescribe a drug described in subsection (i) for the enrollee for the same medical condition; and

(4) in comparison with the discontinued individual contract or group contract, the enrollment in the comparable individual

contract or group contract has the effect of a limitation or exclusion of coverage described in subsection (h)(2) through (h)(5);

the health maintenance organization shall grant a coverage exception for the drug under the comparable individual contract or group contract.

(m) If a coverage exception is granted or considered to have been granted, the health maintenance organization shall provide coverage under the comparable individual contract or group contract that is not more restrictive than the coverage provided for the prescribed drug under the discontinued individual contract or group contract.

(n) This section does not do any of the following:

(1) Prevent a health provider from prescribing a drug for an enrollee if the health provider considers the drug to be medically appropriate to treat the enrollee.

(2) Prevent a pharmacist from substituting:

(A) generic drugs in accordance with IC 16-42-22; or

(B) biosimilar biological products in accordance with IC 16-42-25.

(3) Prevent a health maintenance organization from:

(A) adding a drug to an individual contract's, or a group contract's, formulary; or

(B) removing a drug from an individual contract's, or a group contract's, formulary if the drug manufacturer has removed the drug from sale in the United States.

(o) A violation of this section by a health maintenance organization is an unfair and deceptive act or practice in the business of insurance under IC 27-4-1-4.