February 28, 2020

ENGROSSED
HOUSE BILL No. 1207

DIGEST OF HB 1207 (Updated February 26, 2020 2:52 pm - DI 107)

Citations Affected: IC 5-10; IC 16-18; IC 16-41; IC 25-1; IC 25-26; IC 27-1; IC 27-2; IC 27-8; IC 27-13; IC 34-30; noncode.

Synopsis: Pharmacy matters. Provides that a state employee plan, a health maintenance organization, an insurer, or a pharmacy benefits manager (health plan provider) may not require a pharmacy or pharmacist to collect a higher copayment for a prescription drug from a covered individual than the health plan provider allows the pharmacy or pharmacist to retain. Allows a pharmacist who meets certain requirements to dispense auto-injectable epinephrine by standing order to a person who: (1) has completed a course on auto-injectable epinephrine; and (2) is an individual in a position to assist an individual who is at risk of experiencing anaphylaxis. Allows a person to administer auto-injectable epinephrine to an individual who is experiencing anaphylaxis if certain conditions are met. Requires the state department of health (state department) to issue a statewide

(Continued next page)

Effective: Upon passage; July 1, 2020; January 1, 2021.

Davisson, Barrett

(SENATE SPONSORS — GROOMS, RUCKELSHAUS, ROGERS, BOHACEK)

January 16, 2020, read first time and referred to Committee on Public Health.
January 23, 2020, amended, reported — Do Pass.
January 27, 2020, read second time, ordered engrossed.
January 28, 2020, engrossed. Read third time, passed. Yeas 98, nays 0.

SENATE ACTION

February 5, 2020, read first time and referred to Committee on Health and Provider Services.
February 13, 2020, reassigned to Committee on Insurance and Financial Institutions pursuant to Rule 68(b).
February 27, 2020, amended, reported favorably — Do Pass.

standing order authorizing the dispensing of auto-injectable epinephrine. Authorizes the state health commissioner and certain designated public health authorities to issue a statewide standing order authorizing the dispensing of auto-injectable epinephrine. Extends certain immunities to the state department, the state health commissioner, and certain designated public health authorities. Requires the state department to approve courses concerning the administration of auto-injectable epinephrine. Requires a person to have successfully completed the course to be immune from civil liability. Adds exceptions to the requirement that controlled substance prescriptions be in an electronic format. Provides that the board of pharmacy, in consultation with the medical licensing board, may adopt emergency rules. Adds advanced practice registered nurses and physician assistants to the list of out-of-state providers whose prescriptions a pharmacist has a duty to honor. Allows a prescription for a patient to be transferred electronically or by facsimile by a pharmacy to another pharmacy if the pharmacies do not share a common data base. Allows a licensed pharmacy technician to transfer the prescription. Allows a pharmacist to substitute a therapeutic alternative for epinephrine products for a patient. Allows a pharmacy technician to administer an influenza immunization to an individual under a drug order or prescription, subject to rules adopted by the board of pharmacy. Requires a health plan to establish a procedure for a covered individual to submit a claim for the cost of a covered prescription drug purchased outside of the health plan to offset the covered individual's deductible. Allows a pharmacist to prescribe sterile water for injection with a prescription drug. Requires a state employee health plan to establish a procedure for a covered individual to submit a claim for the cost of a covered prescription drug purchased outside of the state employee health plan to offset the covered individual's deductible. Requires a health plan to provide a covered individual with not less than 60 days' notice prior to the health plan's formulary modification to a prescription drug. Requires a health plan to provide a process on its Internet web site through which a covered individual can request an exception to a formulary modification. Requires a health plan to grant a request for an exception to a formulary modification in certain instances.

February 28, 2020

Second Regular Session of the 121st General Assembly (2020)

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 2019 Regular Session of the General Assembly.

ENGROSSED
HOUSE BILL No. 1207

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

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

SECTION 1. IC 5-10-8-20, AS ADDED BY P.L.209-2018, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 20. (a) As used in this section, "covered individual" means an individual entitled to coverage under a state employee plan.

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

(c) As used in this section, "pharmacy" refers to a pharmacist or pharmacy that has entered into an agreement with a state employee plan to provide drugs to individuals covered under a state employee plan.

(d) As used in this section, "state employee 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 plan.

(e) A pharmacy or pharmacist shall have the right to provide a covered individual with information concerning the amount of the covered individual's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be proscribed by a pharmacy benefits manager from discussing this information or from selling to the covered individual a more affordable alternative if an affordable alternative is available.

(f) A pharmacy benefits manager that covers prescription drugs may not include a provision that requires a covered individual to make payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:

(1) the contracted copayment amount; or

(2) the amount of total approved charges by the pharmacy benefits manager at the point of sale.

This subsection does not prohibit the adjudication of claims in accordance with the state employee plan administered by a pharmacy benefits manager. The covered individual is not liable for any additional charges or entitled to any credits as a result of the adjudicated claim.

(g) The state employee plan or a pharmacy benefits manager may not require a pharmacy or pharmacist to collect a higher copayment for a prescription drug from a covered individual than the state employee plan or pharmacy benefits manager allows the pharmacy or pharmacist to retain.

SECTION 2. IC 5-10-8-23 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 23. (a) As used in this section, "covered individual" means an individual who is entitled to coverage under a state employee health plan.**

(b) As used in this section, "state employee health plan" means the following:

(1) A self-insurance program established under section 7(b) of this chapter.

(2) A contract for prepaid health services under section 7(c) of this chapter.

(c) A state employee health plan shall implement a procedure to allow a covered individual to submit a claim to offset the covered individual's deductible for the cost of a purchase by the covered individual of a prescription drug that:

(1) is covered under the state employee health plan; and

(2) was purchased by the covered individual without

submitting at the point of purchase the claim through the state employee health plan.

(d) If a covered individual submits a claim to the state employee health plan in accordance with the procedure established under subsection (c), the state employee health plan shall verify the purchase described under subsection (c) and count the cost of the purchased covered prescription drug against the covered individual's deductible.

SECTION 3. IC 16-18-2-338.3, AS ADDED BY P.L.32-2015, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 338.3. **(a)** "Standing order", for purposes of IC 16-31 and IC 16-42-27, means:

(1) a written order; or

(2) an order transmitted by other means of communication;

that is prepared by a person authorized to write a prescription for the distribution and administration of an overdose intervention drug, including any actions and interventions to be used in order to ensure timely access to treatment.

(b) "Standing order", for purposes of IC 16-41-43, means:

(1) a written order; or

(2) an order transmitted by other means of communication;

that is prepared by a person authorized to write a prescription for the distribution and administration of auto-injectable epinephrine, including any actions and interventions to be used in order to ensure timely access to treatment.

SECTION 4. IC 16-41-43-2.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 2.3. (a) A pharmacist may, by standing order, dispense auto-injectable epinephrine without examining the individual to whom it may be administered if all of the following conditions are met:**

(1) The auto-injectable epinephrine is dispensed to a person who:

(A) presents a certificate of completion issued under section 2.5(c) of this chapter to the pharmacist before the auto-injectable epinephrine is dispensed; and

(B) is an individual who is or may be in a position to assist an individual who is at risk of experiencing anaphylaxis.

(2) The pharmacist provides instruction concerning how to properly administer auto-injectable epinephrine from the specific device being dispensed at the time of the device's dispensing.

(3) The pharmacist instructs the individual receiving the auto-injectable epinephrine to summon emergency medical services either immediately before or immediately after administering the auto-injectable epinephrine to an individual experiencing anaphylaxis.

(b) A person wishing to receive auto-injectable epinephrine by standing order must do the following:

(1) Successfully complete the course described in section 2.5(a) of this chapter.

(2) Present a certificate of completion issued under section 2.5(c) of this chapter to a pharmacist at the time the auto-injectable epinephrine is requested.

(c) An individual described in subsection (a)(1) may administer auto-injectable epinephrine to an individual that the person reasonably believes is experiencing anaphylaxis.

(d) An individual described in subsection (a)(1) may not be considered to be practicing medicine without a license in violation of IC 25-22.5-8-2 if the individual, acting in good faith:

(1) obtains auto-injectable epinephrine from a pharmacist by standing order;

(2) administers auto-injectable epinephrine to an individual that the person reasonably believes is experiencing anaphylaxis in a manner that is consistent with:

(A) the training provided during the course described in section 2.5(a) of this chapter; or

(B) the instruction provided to the person by a pharmacist at the time the auto-injectable epinephrine was dispensed; and

(3) attempts to summon emergency medical services either immediately before or immediately after administering the auto-injectable epinephrine.

(e) The state department shall ensure that a statewide standing order for the dispensing of auto-injectable epinephrine in Indiana is issued under this section. The state health commissioner may, as part of the individual's official capacity, issue a statewide standing order that may be used for the dispensing of auto-injectable epinephrine under this section. The immunity provided in IC 34-13-3-3 applies to an individual described in this subsection.

SECTION 5. IC 16-41-43-2.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 2.5. (a) The state department shall approve courses concerning allergies and the administration**

of auto-injectable epinephrine that are offered by an approved organization (as defined in IC 25-1-4-0.2).

(b) The state department shall do the following:

(1) Maintain, on the agency's Internet web site, a list of all approved courses.

(2) Prescribe the certification process for the course described in subsection (a).

(3) Revoke the certification of an organization that fails to comply with any certification prerequisite specified by the state department.

(c) A person who successfully completes a certified course shall receive a certificate of completion. The state department may contract with a third party for the purpose of creating or manufacturing the certificate of completion, which must meet the requirements set forth in subsection (d).

(d) A certificate of completion issued under subsection (c) must:

(1) have dimensions that permit the certificate of completion to be carried in a wallet; and

(2) display the following information:

(A) The first and last name of the person.

(B) The first and last name of the course instructor.

(C) The name of the entity responsible for providing the course, if applicable.

(D) The date the course described in subsection (a) was completed.

(E) Any other information required by the state department.

(e) The state department may adopt rules under IC 4-22-2, including emergency rules under IC 4-22-2-37.1, to implement this section.

SECTION 6. IC 16-41-43-3.5, AS ADDED BY P.L.117-2017, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 3.5. Injectable epinephrine that is filled and used in accordance with this chapter must have an expiration date of not less than twelve (12) months from the date that the pharmacy dispenses the injectable epinephrine to the entity **or person, as applicable.**

SECTION 7. IC 16-41-43-5.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 5.5. (a) This chapter does not apply to a person who is eligible for immunity specified in one (1) or more of the following sections:**

(1) Section 6 of this chapter.

(2) IC 20-34-4.5-4.

(3) IC 21-44.5-2-6.

(b) Except as provided in subsection (d), a person who meets all of the following criteria is not liable for civil damages for any act or omission related to the administration of auto-injectable epinephrine:

(1) The person has successfully completed a course described in section 2.5(a) of this chapter before administering auto-injectable epinephrine to a person.

(2) The person administered the auto-injectable epinephrine in a manner that was consistent with:

(A) the training provided during the course described in section 2.5(a) of this chapter; or

(B) the instruction provided to the person by the pharmacist at the time the auto-injectable epinephrine was dispensed to the person.

(3) The person reasonably believed that the recipient of the auto-injectable epinephrine was suffering from anaphylaxis at the time the auto-injectable epinephrine was administered.

(c) A pharmacist who complies with section 2.3(a) of this chapter is not liable for civil damages resulting from the administration of auto-injectable epinephrine.

(d) The immunity described in subsection (b) or (c) does not apply to any act or omission that constitutes gross negligence or willful and wanton misconduct.

SECTION 8. IC 25-1-9.3-8, AS ADDED BY P.L.28-2019, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 8. A prescriber may issue a prescription for a controlled substance in a written format, a faxed format, or an oral order if any of the following apply:

(1) The prescriber cannot transmit an electronically transmitted prescription due to:

(A) temporary technological or electrical failure; **or**

(B) the technological inability to issue a prescription electronically, including but not limited to failure to possess the requisite technology.

(2) The prescriber issues a prescription to be dispensed by a pharmacy located outside Indiana.

(3) The prescriber and the pharmacist are the same entity.

(4) The prescriber issues a prescription that meets any of the following:

(A) The prescription contains elements that are not supported

by the technical standards developed by the National Council for Prescription Drug Programs for electronically transmitted prescriptions (NCPDP SCRIPT).

(B) The federal Food and Drug Administration requires the prescription to contain certain elements that cannot be supported in an electronically transmitted prescription.

(C) The prescription is a non-patient specific prescription in response to a public health emergency or another instance allowable under state law and that requires a non-patient specific prescription under:

(i) a standing order;

(ii) approved protocol for drug therapy;

(iii) collaborative drug management; or

(iv) comprehensive medication management.

(D) The prescription is issued under a research protocol.

(5) The prescriber has received a waiver or a renewal of a previously received waiver from the board in accordance with rules adopted under section 9 of this chapter.

(6) The board, in accordance with rules adopted under section 9 of this chapter, has determined that issuing an electronically transmitted prescription would be impractical and cause delay, adversely impacting the patient's medical condition.

(7) The prescriber reasonably determines that it would be impractical for the patient to obtain an electronic prescription in a timely manner and the delay would adversely affect the patient's medical condition.

SECTION 9. IC 25-1-9.3-9, AS ADDED BY P.L.28-2019, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 9. (a) The board shall, in consultation with the medical licensing board, adopt rules under IC 4-22-2 to implement this chapter, including:

(1) a process to grant or deny waivers or renewals of waivers from the requirement to issue electronically transmitted prescriptions for controlled substances due to:

(A) economic hardship;

(B) technological limitations outside the control of the prescriber; or

(C) other circumstances determined by the board; and

(2) a list of circumstances in which issuing an electronically transmitted prescription would be impractical and cause delay that would adversely impact the user's medical condition.

(b) Any rules adopted under this chapter must be substantially

similar to the requirements and exceptions under 42 U.S.C. 1395w-104.

(c) The board, in consultation with the medical licensing board, may adopt emergency rules in the manner provided in IC 4-22-2-37.1. A rule adopted under this section expires on the earlier of the following:

(1) The date that the rule is superseded, amended, or repealed by a permanent rule adopted under IC 4-22-2.

(2) July 1, 2023.

SECTION 10. IC 25-26-13-16 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 16. (a) A pharmacist shall exercise ~~his~~ **the pharmacist's** professional judgment in the best interest of the patient's health when engaging in the practice of pharmacy.

(b) A pharmacist has a duty to honor all prescriptions from a practitioner or from a physician, podiatrist, dentist, **advanced practice registered nurse, physician assistant,** or veterinarian licensed under the laws of another state. Before honoring a prescription, the pharmacist shall take reasonable steps to determine whether the prescription has been issued in compliance with the laws of the state where it originated. The pharmacist is immune from criminal prosecution or civil liability if ~~he,~~ **the pharmacist,** in good faith, refuses to honor a prescription because, in ~~his~~ **the pharmacist's** professional judgment, the honoring of the prescription would:

(1) be contrary to law;

(2) be against the best interest of the patient;

(3) aid or abet an addiction or habit; or

(4) be contrary to the health and safety of the patient.

SECTION 11. IC 25-26-13-24.8, AS ADDED BY P.L.28-2019, SECTION 16, AND P.L.246-2019, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 24.8. **(a)** Upon request of a patient, a pharmacy shall transfer to another pharmacy a prescription for the patient that the pharmacy has received but not filled unless:

(1) prohibited in writing on the prescription by the prescriber; or

(2) otherwise prohibited by federal law.

(b) Unless prohibited by federal law, a prescription for a patient may be transferred electronically or by facsimile by a pharmacy to another pharmacy if the pharmacies do not share a common data base.

(c) A licensed pharmacy technician may transfer a prescription under subsection (b).

SECTION 12. IC 25-26-13-25.3, AS ADDED BY P.L.246-2019, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 25.3. **(a)** ~~Beginning January 1, 2020,~~ A pharmacy may not dispense injectable epinephrine or glucagon to a person unless:

(1) the injectable epinephrine or glucagon has an expiration date of not less than twelve (12) months from the date that the drug is dispensed; or

(2) the person consents to the injectable epinephrine or glucagon having an expiration date of less than twelve (12) months from the date that the drug is dispensed.

(b) Except as provided in IC 25-26-16.5, a pharmacist may substitute a therapeutic alternative (as defined in IC 25-26-16.5-4) for epinephrine products for a patient.

SECTION 13. IC 25-26-13-31, AS AMENDED BY P.L.247-2019, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 31. (a) A pharmacist may do the following:

(1) Obtain and maintain patient drug histories and other pharmacy records that are related to drug or device therapies.

(2) Perform drug evaluation, drug utilization review, and drug regimen review.

(3) Participate in the selection, storage, and distribution of drugs, dietary supplements, and devices. However, drug selection must comply with IC 16-42-19 and IC 16-42-22.

(4) Participate in drug or drug related research.

(5) Prescribe any of the following devices or supplies approved by the federal Food and Drug Administration:

(A) Inhalation spacer.

(B) Nebulizer.

(C) Supplies for medical devices, including but not limited to, continuous positive airway pressure (CPAP) machine supplies and insulin pump supplies.

(D) Normal saline and sterile water for irrigation for wound care **or for injection with a prescription drug or device.**

(E) Diabetes blood sugar testing supplies.

(F) Pen needles.

(G) Syringes for medication use.

However, the pharmacist must provide the patient with a written advance beneficiary notice that is signed by the patient and that states that the patient may not be eligible for reimbursement for the device or supply. The pharmacy must keep a copy of the patient's advance beneficiary notice on file for seven (7) years.

(b) A pharmacist who participates in an activity allowed under subsection (a) is required to follow the standards for the competent practice of pharmacy adopted by the board.

(c) A pharmacist may issue a prescription for purposes of subsection (a)(5).

SECTION 14. IC 25-26-13-31.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 31.7. (a) Subject to rules adopted under subsection (c), a pharmacy technician may administer an influenza immunization to an individual under a drug order or prescription.**

(b) Subject to rules adopted under subsection (c), a pharmacy technician may administer an influenza immunization to an individual or a group of individuals under a drug order, under a prescription, or according to a protocol approved by a physician.

(c) The board shall adopt rules under IC 4-22-2 to establish requirements applying to a pharmacy technician who administers an influenza immunization to an individual or group of individuals. The rules adopted under this section must provide for the direct supervision of the pharmacy technician by a pharmacist, a physician, a physician assistant, or an advanced practice registered nurse.

(d) The board must approve all programs that provide training to pharmacy technicians to administer influenza immunizations as permitted by this section.

SECTION 15. IC 27-1-24.8-5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 5. A pharmacy benefits manager may not require a pharmacy or pharmacist to collect a higher copayment for a prescription drug from a customer than the pharmacy benefits manager allows the pharmacy or pharmacist to retain.**

SECTION 16. IC 27-2-9.1 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2021]:

Chapter 9.1. Prescription Drug Purchases

Sec. 1. As used in this chapter, "covered individual" means an individual who is entitled to coverage under a health plan.

Sec. 2. As used in this chapter, "health plan" means a plan that is compliant with the PPACA and offered by an insurer to provide, deliver, arrange for, pay for, or reimburse the cost of health care items or services. The term includes the following:

(1) A policy of accident and sickness insurance (as defined in IC 27-8-5-1).

(2) An individual contract (as defined by IC 27-13-1-21) and a group contract (as defined by IC 27-13-1-16).

Sec. 3. As used in this chapter, "insurer" means an entity licensed in Indiana to issue a health plan.

Sec. 4. As used in this chapter, "PPACA" refers to the federal Patient Protection and Affordable Care Act (P.L. 111-148), as amended thereafter, including by the federal Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

Sec. 5. (a) A health plan shall implement a procedure to allow a covered individual to submit a claim to offset the covered individual's deductible for the cost of a purchase by the covered individual of a prescription drug that:

(1) is covered under the covered individual's health plan; and

(2) was purchased by the covered individual without submitting at the point of purchase the claim through the health plan.

(b) If a covered individual submits a claim to the health plan in accordance with the procedure established under subsection (a), the health plan shall verify the purchase described under subsection (a) and count the cost of the purchased covered prescription drug against the covered individual's deductible.

SECTION 17. IC 27-2-9.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 9.5. Formulary Modifications for Prescription Drugs

Sec. 1. For purposes of this chapter, "covered individual" means an individual who is entitled to coverage under a health plan.

Sec. 2. For purposes of this chapter, "formulary modification" includes the following with respect to a prescription drug:

(1) The exclusion of coverage for a drug.

(2) Changing:

(A) a copayment amount;

(B) a coinsurance rate;

(C) drug cost sharing minimum or maximum amounts;

(D) a deductible; or

(E) a maximum out-of-pocket amount in a manner as to raise the covered individual's out-of-pocket costs for a drug.

(3) The movement of a drug to a more restrictive coverage category or tier.

(4) The discontinuation of coverage of a drug before the date on which a covered individual is no longer entitled to coverage.

(5) The removal of a drug from a formulary, unless any of the following occur:

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

(B) The 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) A limitation or reduction in the coverage of a drug in any other way, including subjecting it to a new prior authorization or step therapy requirement.

Sec. 3. For purposes of this chapter, "health plan" includes the following:

(1) A policy of accident and sickness insurance (as defined in IC 27-8-5-1).

(2) An individual contract (as defined in IC 27-13-1-21) and a group contract (as defined in IC 27-13-1-16).

Sec. 4. Not later than sixty (60) days prior to the effective date of a formulary modification, a health plan must provide the following to covered individuals affected by the modification:

(1) Notice of the formulary modification.

(2) Information on the process for requesting an exception to the formulary modification (as described in section 5 of this chapter).

(3) A list of alternative covered drugs for the medical condition in question.

Sec. 5. A health plan must provide, on its Internet web site, a clear and accessible process through which a covered individual may request an exception to a formulary modification. A health plan's existing exceptions process may be used to satisfy the requirements of this section.

Sec. 6. A health plan must grant an exception to a formulary modification if any of the following apply:

(1) The alternative covered drugs provided in the list required by section 4(3) of this chapter are contraindicated or will likely cause an adverse reaction or physical or mental harm to the covered individual.

(2) The alternative covered drugs provided in the list required

by section 4(3) of this chapter are expected to be ineffective, based on both of the following:

(A) The known clinical characteristics of the covered individual.

(B) The known characteristics of the alternative covered drugs, as found in sound clinical evidence.

(3) The covered individual has previously received the alternative covered drugs provided in the list required by section 4(3) of this chapter, or a drug in the same pharmacologic class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) Based on clinical appropriateness, the alternative covered drugs provided in the list required by section 4(3) of this chapter are not in the best interest of the covered individual because the covered individual's use of the alternative covered drugs is expected to do any of the following:

(A) Cause a significant barrier to the covered individual's adherence to or compliance with the covered individual's plan of care.

(B) Worsen a comorbid condition of the covered individual.

(C) Decrease the covered individual's ability to achieve or maintain reasonable functional ability in performing daily activities.

Sec. 7. (a) A health plan must make a determination regarding a covered individual's request for an exception to a formulary modification not later than:

(1) for an urgent care situation, one (1) business day after receiving the request; or

(2) for a nonurgent care situation, three (3) business days after receiving the request.

(b) If a health plan does not issue a determination within the time required by subsection (a), a covered individual's request for an exception to a formulary modification is considered to have been granted.

(c) If a health plan denies a covered individual's request for an exception to a formulary modification, the health plan must provide the covered individual and the covered individual's prescribing provider with notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(d) Except when a drug has been removed from a formulary because of concerns about safety, if a drug has been removed from a formulary and a request for an exception to the formulary modification was submitted by or on behalf of a covered individual prior to the effective date of the change, a health plan must continue to provide coverage for that drug until the health plan renders a decision on the covered individual's request for an exception to the formulary modification.

Sec. 8. When an exception to a formulary modification is granted, a health plan:

(1) may not issue a formulary modification for coverage of the drug; and

(2) must authorize coverage of the drug;

for the remainder of the covered individual's policy year.

Sec. 9. (a) Nothing in this chapter prevents a covered individual's:

(1) prescribing provider from prescribing a drug that the prescribing provider considers to be medically necessary for the covered individual; or

(2) pharmacist from substituting:

(A) a generic drug under IC 16-42-22; or

(B) a biosimilar biological product under IC 16-42-25.

(b) Nothing in this chapter prevents a health plan from doing any of the following:

(1) Adding a drug to the health plan's formulary.

(2) Removing a drug from the health plan's formulary if the drug's manufacturer has removed the drug from sale in the United States.

SECTION 18. IC 27-8-11-12, AS ADDED BY P.L.209-2018, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 12. (a) As used in this section, "drug" means a prescription drug.

(b) As used in this section, "insurer" refers to an insurer that provides coverage for drugs. The term includes a person that administers drug benefits on behalf of an insurer.

(c) As used in this section, "pharmacy" refers to a pharmacist or pharmacy that has entered into an agreement with an insurer under section 3 of this chapter.

(d) A pharmacy or pharmacist shall have the right to provide an insured with information concerning the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be proscribed by an insurer from discussing this information or

from selling to the insured a more affordable alternative if an affordable alternative is available.

(e) An insurer that covers prescription drugs may not include a provision that requires an insured to make payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:

(1) the contracted copayment amount; or

(2) the amount of total approved charges by the insurer at the point of sale.

This subsection does not prohibit the adjudication of claims in accordance with an accident and sickness insurance policy issued or administered by an insurer. The insured is not liable for any additional charges or entitled to any credits as a result of the adjudicated claim.

(f) The insurer or a pharmacy benefits manager may not require a pharmacy or pharmacist to collect a higher copayment for a prescription drug from an insured than the insurer or pharmacy benefits manager allows the pharmacy or pharmacist to retain.

SECTION 19. IC 27-13-15-6, AS ADDED BY P.L.209-2018, SECTION 13, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 6. (a) As used in this section, "drug" means a prescription drug.

(b) As used in this section, "health maintenance organization" refers to a health maintenance organization that provides coverage for drugs. The term includes the following:

(1) A limited service health maintenance organization.

(2) A person that administers drug benefits on behalf of a health maintenance organization or a limited service health maintenance organization.

(c) As used in this section, "pharmacy" refers to a pharmacist or pharmacy that is a participating provider.

(d) A pharmacy or pharmacist shall have the right to provide an enrollee with information concerning the amount of the enrollee's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be proscribed by a health maintenance organization from discussing this information or from selling to the enrollee a more affordable alternative if an affordable alternative is available.

(e) A health maintenance organization that covers prescription drugs may not include a provision that requires an enrollee to make payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:

(1) the contracted copayment amount; or

(2) the amount of total approved charges by the health

maintenance organization at the point of sale.

This subsection does not prohibit the adjudication of claims in accordance with an individual contract or group contract issued or administered by a health maintenance organization. The enrollee is not liable for any additional charges or entitled to any credits as a result of the adjudicated claim.

(f) The health maintenance organization or a pharmacy benefits manager may not require a pharmacy or pharmacist to collect a higher copayment for a prescription drug from an enrollee than the health maintenance organization or pharmacy benefits manager allows the pharmacy or pharmacist to retain.

SECTION 20. IC 34-30-2-83.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 83.6. IC 16-41-43-5.5 (Concerning the administration of auto-injectable epinephrine by laypersons and the dispensing of auto-injectable epinephrine by pharmacists).**

SECTION 21. [EFFECTIVE JULY 1, 2020] **(a) IC 5-10-8-23, as added by this act, applies to a state employee health plan that is established, entered into, amended, or renewed after June 30, 2020.**

(b) IC 27-2-9.1 and IC 27-2-9.5, as added by this act, apply to a health plan that is issued, entered into, delivered, amended, or renewed after June 30, 2020.

(c) This SECTION expires June 30, 2023.

SECTION 22. **An emergency is declared for this act.**

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1207, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 2, between lines 25 and 26, begin a new paragraph and insert:

"SECTION 2. IC 16-18-2-338.3, AS ADDED BY P.L.32-2015, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 338.3. **(a)** "Standing order", for purposes of IC 16-31 and IC 16-42-27, means:

(1) a written order; or

(2) an order transmitted by other means of communication;

that is prepared by a person authorized to write a prescription for the distribution and administration of an overdose intervention drug, including any actions and interventions to be used in order to ensure timely access to treatment.

(b) "Standing order", for purposes of IC 16-41-43, means:

(1) a written order; or

(2) an order transmitted by other means of communication;

that is prepared by a person authorized to write a prescription for the distribution and administration of auto-injectable epinephrine, including any actions and interventions to be used in order to ensure timely access to treatment.

SECTION 3. IC 16-41-43-2.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 2.3. (a) A pharmacist may, by standing order, dispense auto-injectable epinephrine without examining the individual to whom it may be administered if all of the following conditions are met:**

(1) The auto-injectable epinephrine is dispensed to a person who:

(A) presents a certificate of completion issued under section 2.5(c) of this chapter to the pharmacist before the auto-injectable epinephrine is dispensed; and

(B) is an individual who is or may be in a position to assist an individual who is at risk of experiencing anaphylaxis.

(2) The pharmacist provides instruction concerning how to properly administer auto-injectable epinephrine from the specific device being dispensed at the time of the device's dispensing.

(3) The pharmacist instructs the individual receiving the auto-injectable epinephrine to summon emergency medical

services either immediately before or immediately after administering the auto-injectable epinephrine to an individual experiencing anaphylaxis.

(b) A person wishing to receive auto-injectable epinephrine by standing order must do the following:

(1) Successfully complete the course described in section 2.5(a) of this chapter.

(2) Present a certificate of completion issued under section 2.5(c) of this chapter to a pharmacist at the time the auto-injectable epinephrine is requested.

(c) An individual described in subsection (a)(1) may administer auto-injectable epinephrine to an individual that the person reasonably believes is experiencing anaphylaxis.

(d) An individual described in subsection (a)(1) may not be considered to be practicing medicine without a license in violation of IC 25-22.5-8-2 if the individual, acting in good faith:

(1) obtains auto-injectable epinephrine from a pharmacist by standing order;

(2) administers auto-injectable epinephrine to an individual that the person reasonably believes is experiencing anaphylaxis in a manner that is consistent with:

(A) the training provided during the course described in section 2.5(a) of this chapter; or

(B) the instruction provided to the person by a pharmacist at the time the auto-injectable epinephrine was dispensed; and

(3) attempts to summon emergency medical services either immediately before or immediately after administering the auto-injectable epinephrine.

(e) The state department shall ensure that a statewide standing order for the dispensing of auto-injectable epinephrine in Indiana is issued under this section. The state health commissioner may, as part of the individual's official capacity, issue a statewide standing order that may be used for the dispensing of auto-injectable epinephrine under this section. The immunity provided in IC 34-13-3-3 applies to an individual described in this subsection.

SECTION 4. IC 16-41-43-2.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 2.5. (a) The state department shall approve courses concerning allergies and the administration of auto-injectable epinephrine that are offered by an approved organization (as defined in IC 25-1-4-0.2).**

(b) The state department shall do the following:

(1) Maintain, on the agency's Internet web site, a list of all approved courses.

(2) Prescribe the certification process for the course described in subsection (a).

(3) Revoke the certification of an organization that fails to comply with any certification prerequisite specified by the state department.

(c) A person who successfully completes a certified course shall receive a certificate of completion. The state department may contract with a third party for the purpose of creating or manufacturing the certificate of completion, which must meet the requirements set forth in subsection (d).

(d) A certificate of completion issued under subsection (c) must:

(1) have dimensions that permit the certificate of completion to be carried in a wallet; and

(2) display the following information:

(A) The first and last name of the person.

(B) The first and last name of the course instructor.

(C) The name of the entity responsible for providing the course, if applicable.

(D) The date the course described in subsection (a) was completed.

(E) Any other information required by the state department.

(e) The state department may adopt rules under IC 4-22-2, including emergency rules under IC 4-22-2-37.1, to implement this section.

SECTION 5. IC 16-41-43-3.5, AS ADDED BY P.L.117-2017, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 3.5. Injectable epinephrine that is filled and used in accordance with this chapter must have an expiration date of not less than twelve (12) months from the date that the pharmacy dispenses the injectable epinephrine to the entity **or person, as applicable.**

SECTION 6. IC 16-41-43-5.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 5.5. (a) This chapter does not apply to a person who is eligible for immunity specified in one (1) or more of the following sections:**

(1) Section 6 of this chapter.

(2) IC 20-34-4.5-4.

(3) IC 21-44.5-2-6.

(b) Except as provided in subsection (d), a person who meets all of the following criteria is not liable for civil damages for any act or omission related to the administration of auto-injectable epinephrine:

(1) The person has successfully completed a course described in section 2.5(a) of this chapter before administering auto-injectable epinephrine to a person.

(2) The person administered the auto-injectable epinephrine in a manner that was consistent with:

(A) the training provided during the course described in section 2.5(a) of this chapter; or

(B) the instruction provided to the person by the pharmacist at the time the auto-injectable epinephrine was dispensed to the person.

(3) The person reasonably believed that the recipient of the auto-injectable epinephrine was suffering from anaphylaxis at the time the auto-injectable epinephrine was administered.

(c) A pharmacist who complies with section 2.3(a) of this chapter is not liable for civil damages resulting from the administration of auto-injectable epinephrine.

(d) The immunity described in subsection (b) or (c) does not apply to any act or omission that constitutes gross negligence or willful and wanton misconduct.

SECTION 7. IC 25-1-9.3-8, AS ADDED BY P.L.28-2019, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 8. A prescriber may issue a prescription for a controlled substance in a written format, a faxed format, or an oral order if any of the following apply:

(1) The prescriber cannot transmit an electronically transmitted prescription due to:

(A) temporary technological or electrical failure; **or**

(B) the technological inability to issue a prescription electronically.

(2) The prescriber issues a prescription to be dispensed by a pharmacy located outside Indiana.

(3) The prescriber and the pharmacist are the same entity.

(4) The prescriber issues a prescription that meets any of the following:

(A) The prescription contains elements that are not supported by the technical standards developed by the National Council for Prescription Drug Programs for electronically transmitted prescriptions (NCPDP SCRIPT).

(B) The federal Food and Drug Administration requires the prescription to contain certain elements that cannot be supported in an electronically transmitted prescription.

(C) The prescription is a non-patient specific prescription in response to a public health emergency or another instance allowable under state law and that requires a non-patient specific prescription under:

(i) a standing order;

(ii) approved protocol for drug therapy;

(iii) collaborative drug management; or

(iv) comprehensive medication management.

(D) The prescription is issued under a research protocol.

(5) The prescriber has received a waiver or a renewal of a previously received waiver from the board in accordance with rules adopted under section 9 of this chapter.

(6) The board, in accordance with rules adopted under section 9 of this chapter, has determined that issuing an electronically transmitted prescription would be impractical and cause delay, adversely impacting the patient's medical condition.

(7) The prescriber reasonably determines that it would be impractical for the patient to obtain an electronic prescription in a timely manner and the delay would adversely affect the patient's medical condition.

(8) The prescriber provides notice to the board that the prescriber does not use an electronic medical record.

SECTION 8. IC 25-1-9.3-9, AS ADDED BY P.L.28-2019, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 9. (a) The board shall, in consultation with the medical licensing board, adopt rules under IC 4-22-2 to implement this chapter, including:

(1) a process to grant or deny waivers or renewals of waivers from the requirement to issue electronically transmitted prescriptions for controlled substances due to:

(A) economic hardship;

(B) technological limitations outside the control of the prescriber; or

(C) other circumstances determined by the board; and

(2) a list of circumstances in which issuing an electronically transmitted prescription would be impractical and cause delay that would adversely impact the user's medical condition.

(b) Any rules adopted under this chapter must be substantially similar to the requirements and exceptions under 42 U.S.C.

1395w-104.

(c) The board, in consultation with the medical licensing board, may adopt emergency rules in the manner provided in IC 4-22-2-37.1. A rule adopted under this section expires on the earlier of the following:

(1) The date that the rule is superseded, amended, or repealed by a permanent rule adopted under IC 4-22-2.

(2) July 1, 2023.".

Page 6, delete lines 9 through 32, begin a new paragraph and insert:

"SECTION 18. IC 34-30-2-83.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 83.6. IC 16-41-43-5.5 (Concerning the administration of auto-injectable epinephrine by laypersons and the dispensing of auto-injectable epinephrine by pharmacists).**".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1207 as introduced.)

KIRCHHOFER

Committee Vote: yeas 12, nays 0.

REPORT OF THE PRESIDENT
PRO TEMPORE

Madam President: Pursuant to Senate Rule 68(b), I hereby report that House Bill 1207, currently assigned to the Committee on Health and Provider Services, be reassigned to the Committee on Insurance and Financial Institutions.

BRAY

COMMITTEE REPORT

Madam President: The Senate Committee on Insurance and Financial Institutions, to which was referred House Bill No. 1207, has had the same under consideration and begs leave to report the same

back to the Senate with the recommendation that said bill be AMENDED as follows:

Replace the effective date in SECTION 9 with "[EFFECTIVE UPON PASSAGE]".

Page 2, between lines 25 and 26, begin a new paragraph and insert:

"SECTION 2. IC 5-10-8-23 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 23. (a) As used in this section, "covered individual" means an individual who is entitled to coverage under a state employee health plan.**

(b) As used in this section, "state employee health plan" means the following:

(1) A self-insurance program established under section 7(b) of this chapter.

(2) A contract for prepaid health services under section 7(c) of this chapter.

(c) A state employee health plan shall implement a procedure to allow a covered individual to submit a claim to offset the covered individual's deductible for the cost of a purchase by the covered individual of a prescription drug that:

(1) is covered under the state employee health plan; and

(2) was purchased by the covered individual without submitting at the point of purchase the claim through the state employee health plan.

(d) If a covered individual submits a claim to the state employee health plan in accordance with the procedure established under subsection (c), the state employee health plan shall verify the purchase described under subsection (c) and count the cost of the purchased covered prescription drug against the covered individual's deductible.".

Page 6, line 10, delete "electronically." and insert "**electronically, including but not limited to failure to possess the requisite technology.**".

Page 7, delete lines 1 through 2.

Page 8, between lines 32 and 33, begin a new paragraph and insert:

"SECTION 13. IC 25-26-13-31, AS AMENDED BY P.L.247-2019, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 31. (a) A pharmacist may do the following:

(1) Obtain and maintain patient drug histories and other pharmacy records that are related to drug or device therapies.

(2) Perform drug evaluation, drug utilization review, and drug regimen review.

(3) Participate in the selection, storage, and distribution of drugs, dietary supplements, and devices. However, drug selection must comply with IC 16-42-19 and IC 16-42-22.

(4) Participate in drug or drug related research.

(5) Prescribe any of the following devices or supplies approved by the federal Food and Drug Administration:

(A) Inhalation spacer.

(B) Nebulizer.

(C) Supplies for medical devices, including but not limited to, continuous positive airway pressure (CPAP) machine supplies and insulin pump supplies.

(D) Normal saline and sterile water for irrigation for wound care **or for injection with a prescription drug or device.**

(E) Diabetes blood sugar testing supplies.

(F) Pen needles.

(G) Syringes for medication use.

However, the pharmacist must provide the patient with a written advance beneficiary notice that is signed by the patient and that states that the patient may not be eligible for reimbursement for the device or supply. The pharmacy must keep a copy of the patient's advance beneficiary notice on file for seven (7) years.

(b) A pharmacist who participates in an activity allowed under subsection (a) is required to follow the standards for the competent practice of pharmacy adopted by the board.

(c) A pharmacist may issue a prescription for purposes of subsection (a)(5).".

Page 9, line 4, delete ":".

Page 9, line 5, delete "(1)".

Page 9, run in lines 4 through 5.

Page 9, line 7, delete "; and" and insert "**.**".

Page 9, delete lines 8 through 10.

Page 9, delete lines 11 through 21, begin a new paragraph and insert:

"**(d) The board must approve all programs that provide training to pharmacy technicians to administer influenza immunizations as permitted by this section.**".

Page 9, between lines 28 and 29, begin a new paragraph and insert:

"SECTION 17. IC 27-2-9.1 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2021]:

Chapter 9.1. Prescription Drug Purchases

Sec. 1. As used in this chapter, "covered individual" means an

individual who is entitled to coverage under a health plan.

Sec. 2. As used in this chapter, "health plan" means a plan that is compliant with the PPACA and offered by an insurer to provide, deliver, arrange for, pay for, or reimburse the cost of health care items or services. The term includes the following:

(1) A policy of accident and sickness insurance (as defined in IC 27-8-5-1).

(2) An individual contract (as defined by IC 27-13-1-21) and a group contract (as defined by IC 27-13-1-16).

Sec. 3. As used in this chapter, "insurer" means an entity licensed in Indiana to issue a health plan.

Sec. 4. As used in this chapter, "PPACA" refers to the federal Patient Protection and Affordable Care Act (P.L. 111-148), as amended thereafter, including by the federal Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

Sec. 5. (a) A health plan shall implement a procedure to allow a covered individual to submit a claim to offset the covered individual's deductible for the cost of a purchase by the covered individual of a prescription drug that:

(1) is covered under the covered individual's health plan; and

(2) was purchased by the covered individual without submitting at the point of purchase the claim through the health plan.

(b) If a covered individual submits a claim to the health plan in accordance with the procedure established under subsection (a), the health plan shall verify the purchase described under subsection (a) and count the cost of the purchased covered prescription drug against the covered individual's deductible.

SECTION 18. IC 27-2-9.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 9.5. Formulary Modifications for Prescription Drugs

Sec. 1. For purposes of this chapter, "covered individual" means an individual who is entitled to coverage under a health plan.

Sec. 2. For purposes of this chapter, "formulary modification" includes the following with respect to a prescription drug:

(1) The exclusion of coverage for a drug.

(2) Changing:

(A) a copayment amount;

(B) a coinsurance rate;

(C) drug cost sharing minimum or maximum amounts;

(D) a deductible; or

(E) a maximum out-of-pocket amount in a manner as to raise the covered individual's out-of-pocket costs for a drug.

(3) The movement of a drug to a more restrictive coverage category or tier.

(4) The discontinuation of coverage of a drug before the date on which a covered individual is no longer entitled to coverage.

(5) The removal of a drug from a formulary, unless any of the following occur:

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

(B) The 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) A limitation or reduction in the coverage of a drug in any other way, including subjecting it to a new prior authorization or step therapy requirement.

Sec. 3. For purposes of this chapter, "health plan" includes the following:

(1) A policy of accident and sickness insurance (as defined in IC 27-8-5-1).

(2) An individual contract (as defined in IC 27-13-1-21) and a group contract (as defined in IC 27-13-1-16).

Sec. 4. Not later than sixty (60) days prior to the effective date of a formulary modification, a health plan must provide the following to covered individuals affected by the modification:

(1) Notice of the formulary modification.

(2) Information on the process for requesting an exception to the formulary modification (as described in section 5 of this chapter).

(3) A list of alternative covered drugs for the medical condition in question.

Sec. 5. A health plan must provide, on its Internet web site, a clear and accessible process through which a covered individual may request an exception to a formulary modification. A health plan's existing exceptions process may be used to satisfy the requirements of this section.

Sec. 6. A health plan must grant an exception to a formulary modification if any of the following apply:

(1) The alternative covered drugs provided in the list required by section 4(3) of this chapter are contraindicated or will likely cause an adverse reaction or physical or mental harm to the covered individual.

(2) The alternative covered drugs provided in the list required by section 4(3) of this chapter are expected to be ineffective, based on both of the following:

(A) The known clinical characteristics of the covered individual.

(B) The known characteristics of the alternative covered drugs, as found in sound clinical evidence.

(3) The covered individual has previously received the alternative covered drugs provided in the list required by section 4(3) of this chapter, or a drug in the same pharmacologic class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) Based on clinical appropriateness, the alternative covered drugs provided in the list required by section 4(3) of this chapter are not in the best interest of the covered individual because the covered individual's use of the alternative covered drugs is expected to do any of the following:

(A) Cause a significant barrier to the covered individual's adherence to or compliance with the covered individual's plan of care.

(B) Worsen a comorbid condition of the covered individual.

(C) Decrease the covered individual's ability to achieve or maintain reasonable functional ability in performing daily activities.

Sec. 7. (a) A health plan must make a determination regarding a covered individual's request for an exception to a formulary modification not later than:

(1) for an urgent care situation, one (1) business day after receiving the request; or

(2) for a nonurgent care situation, three (3) business days after receiving the request.

(b) If a health plan does not issue a determination within the time required by subsection (a), a covered individual's request for an exception to a formulary modification is considered to have been granted.

(c) If a health plan denies a covered individual's request for an

exception to a formulary modification, the health plan must provide the covered individual and the covered individual's prescribing provider with notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(d) Except when a drug has been removed from a formulary because of concerns about safety, if a drug has been removed from a formulary and a request for an exception to the formulary modification was submitted by or on behalf of a covered individual prior to the effective date of the change, a health plan must continue to provide coverage for that drug until the health plan renders a decision on the covered individual's request for an exception to the formulary modification.

Sec. 8. When an exception to a formulary modification is granted, a health plan:

(1) may not issue a formulary modification for coverage of the drug; and

(2) must authorize coverage of the drug;

for the remainder of the covered individual's policy year.

Sec. 9. (a) Nothing in this chapter prevents a covered individual's:

(1) prescribing provider from prescribing a drug that the prescribing provider considers to be medically necessary for the covered individual; or

(2) pharmacist from substituting:

(A) a generic drug under IC 16-42-22; or

(B) a biosimilar biological product under IC 16-42-25.

(b) Nothing in this chapter prevents a health plan from doing any of the following:

(1) Adding a drug to the health plan's formulary.

(2) Removing a drug from the health plan's formulary if the drug's manufacturer has removed the drug from sale in the United States.".

Page 11, after line 16, begin a new paragraph and insert:

"SECTION 22. [EFFECTIVE JULY 1, 2020] **(a) IC 5-10-8-23, as added by this act, applies to a state employee health plan that is established, entered into, amended, or renewed after June 30, 2020.**

(b) IC 27-2-9.1 and IC 27-2-9.5, as added by this act, apply to a health plan that is issued, entered into, delivered, amended, or renewed after June 30, 2020.

(c) This SECTION expires June 30, 2023.

SECTION 23. **An emergency is declared for this act.**".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1207 as printed January 24, 2020.)

BASSLER, Chairperson

Committee Vote: Yeas 5, Nays 1.