Reprinted
January 30, 2020

HOUSE BILL No. 1005

DIGEST OF HB 1005 (Updated January 29, 2020 3:03 pm - DI 77)

Citations Affected: IC 5-14; IC 12-26; IC 16-18; IC 16-21; IC 16-24.5; IC 16-47; IC 16-51; IC 25-22.5; IC 25-26; IC 27-1; IC 27-2; IC 27-4; IC 27-8; IC 27-13; IC 36-2.

Synopsis: Health and insurance matters. Establishes the importation of prescription drugs program (program) for the importation of prescription drugs to be administered by the state department of health (state department). Requires the state department to apply to the federal government for approval of the program. Sets forth requirements for the vendor of the program. Sets requirements for suppliers, importers, and wholesale drug distributors of the program. Requires the state department to submit reports to the governor and the general assembly concerning the program. Establishes for participants in the program an international export pharmacy permit and wholesale drug distributor permit administered by the Indiana board of pharmacy. Provides that a facility is an off-campus location of a hospital if: (1) the operations of the facility are directly or indirectly owned or controlled by, or affiliated with, the hospital; (2) the facility provides services that are organizationally and functionally integrated with the services of the hospital; and (3) the facility provides preventive services, diagnostic services, treatment services, or emergency services. Requires hospitals, ambulatory surgical outpatient centers, and urgent care facilities to post certain health care services pricing information by billing code on the
(Continued next page)

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

Schaibley, Lehman, Carbaugh, Shackleford

January 6, 2020, read first time and referred to Committee on Public Health.
January 23, 2020, amended, reported — Do Pass.
January 29, 2020, read second time, amended, ordered engrossed.

Digest Continued

hospital's Internet web site and sets forth requirements. Requires: (1) a provider facility (including a hospital) in which a nonemergency health care service will be performed; or (2) a practitioner (including a physician) who will perform a nonemergency health care service; upon request from the individual for whom the nonemergency health care service has been ordered, scheduled, or referred, to provide a good faith estimate of the price for the nonemergency health care service not more than three business days after receiving the individual's request. Requires a provider facility or practitioner to include the address of the service facility location to obtain reimbursement for a commercial claim for health care services. Requires a health carrier (including an insurer or a health maintenance organization) to provide to an individual who is entitled to coverage from the health carrier, not more than three business days after the individual requests the information, a good faith estimate of: (1) the amount of the cost of the nonemergency health care service that the health carrier will pay for or reimburse to the covered individual; or (2) the extent and nature of the ordered nonemergency health care service a covered individual is entitled to receive. Requires the department of insurance to submit a request for information and a request for proposal concerning the establishment and implementation of an all payer claims data base and sets forth requirements. Provides that if a health carrier provides coverage to the individual through a network plan, the health carrier shall inform the individual whether the provider facility in which the nonemergency health care service will be provided and the practitioners who will provide the nonemergency health care service are included in the health carrier's network plan. Requires provider facilities to post signs in waiting rooms and to provide Internet web site notices about the availability of estimates of the amount the patient will be charged for medical services. Requires practitioners to provide notice about the availability of estimates of the amount the patient will be charged for medical services when the practitioner has ordered, scheduled, or referred the individual for a nonemergency health care service. Requires health carriers to provide Internet web site notices about the availability of good faith estimates of coverage for nonemergency health care services. Provides penalties for noncompliance by provider facilities, practitioners, and health carriers. Requires an insurance producer to disclose commission information. Prohibits health provider contracts and contracts between a provider and a pharmacy benefits manager from including provisions that prohibit the disclosure of health care service claims data to employers providing the health coverage and makes a violation an unfair and deceptive act. Provides that a fully credentialed provider shall be reimbursed by an insurer or health maintenance organization for eligible services provided at an in-network hospital if certain conditions are met.

Reprinted
January 30, 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.

HOUSE BILL No. 1005

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

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

SECTION 1. IC 5-14-3-2, AS AMENDED BY P.L.85-2017, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 2. (a) The definitions set forth in this section apply throughout this chapter.

(b) "Copy" includes transcribing by handwriting, photocopying, xerography, duplicating machine, duplicating electronically stored data onto a disk, tape, drum, or any other medium of electronic data storage, and reproducing by any other means.

(c) "Criminal intelligence information" means data that has been evaluated to determine that the data is relevant to:

(1) the identification of; and

(2) the criminal activity engaged in by;

an individual who or organization that is reasonably suspected of involvement in criminal activity.

(d) "Direct cost" means one hundred five percent (105%) of the sum

of the cost of:

(1) the initial development of a program, if any;

(2) the labor required to retrieve electronically stored data; and

(3) any medium used for electronic output;

for providing a duplicate of electronically stored data onto a disk, tape, drum, or other medium of electronic data retrieval under section 8(g) of this chapter, or for reprogramming a computer system under section 6(c) of this chapter.

(e) "Electronic map" means copyrighted data provided by a public agency from an electronic geographic information system.

(f) "Enhanced access" means the inspection of a public record by a person other than a governmental entity and that:

(1) is by means of an electronic device other than an electronic device provided by a public agency in the office of the public agency; or

(2) requires the compilation or creation of a list or report that does not result in the permanent electronic storage of the information.

(g) "Facsimile machine" means a machine that electronically transmits exact images through connection with a telephone network.

(h) "Inspect" includes the right to do the following:

(1) Manually transcribe and make notes, abstracts, or memoranda.

(2) In the case of tape recordings or other aural public records, to listen and manually transcribe or duplicate, or make notes, abstracts, or other memoranda from them.

(3) In the case of public records available:

(A) by enhanced access under section 3.5 of this chapter; or

(B) to a governmental entity under section 3(c)(2) of this chapter;

to examine and copy the public records by use of an electronic device.

(4) In the case of electronically stored data, to manually transcribe and make notes, abstracts, or memoranda or to duplicate the data onto a disk, tape, drum, or any other medium of electronic storage.

(i) "Investigatory record" means information compiled in the course of the investigation of a crime.

(j) "Law enforcement activity" means:

(1) a traffic stop;

(2) a pedestrian stop;

(3) an arrest;

(4) a search;

(5) an investigation;

(6) a pursuit;

(7) crowd control;

(8) traffic control; or

(9) any other instance in which a law enforcement officer is enforcing the law.

The term does not include an administrative activity, including the completion of paperwork related to a law enforcement activity, or a custodial interrogation conducted in a place of detention as described in Indiana Evidence Rule 617, regardless of the ultimate admissibility of a statement made during the custodial interrogation.

(k) "Law enforcement recording" means an audio, visual, or audiovisual recording of a law enforcement activity captured by a camera or other device that is:

(1) provided to or used by a law enforcement officer in the scope of the officer's duties; and

(2) designed to be worn by a law enforcement officer or attached to the vehicle or transportation of a law enforcement officer.

(l) "Offender" means a person confined in a penal institution as the result of the conviction for a crime.

(m) "Patient" has the meaning set out in IC 16-18-2-272(d).

(n) "Person" means an individual, a corporation, a limited liability company, a partnership, an unincorporated association, or a governmental entity.

(o) "Private university police department" means the police officers appointed by the governing board of a private university under IC 21-17-5.

(p) "Provider" has the meaning set out in ~~IC 16-18-2-295(b)~~ **IC 16-18-2-295(c)** and includes employees of the state department of health or local boards of health who create patient records at the request of another provider or who are social workers and create records concerning the family background of children who may need assistance.

(q) "Public agency", except as provided in section 2.1 of this chapter, means the following:

(1) Any board, commission, department, division, bureau, committee, agency, office, instrumentality, or authority, by whatever name designated, exercising any part of the executive, administrative, judicial, or legislative power of the state.

(2) Any:

(A) county, township, school corporation, city, or town, or any board, commission, department, division, bureau, committee, office, instrumentality, or authority of any county, township,

school corporation, city, or town;

(B) political subdivision (as defined by IC 36-1-2-13); or

(C) other entity, or any office thereof, by whatever name designated, exercising in a limited geographical area the executive, administrative, judicial, or legislative power of the state or a delegated local governmental power.

(3) Any entity or office that is subject to:

(A) budget review by either the department of local government finance or the governing body of a county, city, town, township, or school corporation; or

(B) an audit by the state board of accounts that is required by statute, rule, or regulation.

(4) Any building corporation of a political subdivision that issues bonds for the purpose of constructing public facilities.

(5) Any advisory commission, committee, or body created by statute, ordinance, or executive order to advise the governing body of a public agency, except medical staffs or the committees of any such staff.

(6) Any law enforcement agency, which means an agency or a department of any level of government that engages in the investigation, apprehension, arrest, or prosecution of alleged criminal offenders, such as the state police department, the police or sheriff's department of a political subdivision, prosecuting attorneys, members of the excise police division of the alcohol and tobacco commission, conservation officers of the department of natural resources, gaming agents of the Indiana gaming commission, gaming control officers of the Indiana gaming commission, and the security division of the state lottery commission.

(7) Any license branch operated under IC 9-14.1.

(8) The state lottery commission established by IC 4-30-3-1, including any department, division, or office of the commission.

(9) The Indiana gaming commission established under IC 4-33, including any department, division, or office of the commission.

(10) The Indiana horse racing commission established by IC 4-31, including any department, division, or office of the commission.

(11) A private university police department. The term does not include the governing board of a private university or any other department, division, board, entity, or office of a private university.

(r) "Public record" means any writing, paper, report, study, map, photograph, book, card, tape recording, or other material that is

created, received, retained, maintained, or filed by or with a public agency and which is generated on paper, paper substitutes, photographic media, chemically based media, magnetic or machine readable media, electronically stored data, or any other material, regardless of form or characteristics.

(s) "Standard-sized documents" includes all documents that can be mechanically reproduced (without mechanical reduction) on paper sized eight and one-half (8 1/2) inches by eleven (11) inches or eight and one-half (8 1/2) inches by fourteen (14) inches.

(t) "Trade secret" has the meaning set forth in IC 24-2-3-2.

(u) "Work product of an attorney" means information compiled by an attorney in reasonable anticipation of litigation. The term includes the attorney's:

(1) notes and statements taken during interviews of prospective witnesses; and

(2) legal research or records, correspondence, reports, or memoranda to the extent that each contains the attorney's opinions, theories, or conclusions.

This definition does not restrict the application of any exception under section 4 of this chapter.

SECTION 2. IC 12-26-2-5, AS AMENDED BY P.L.1-2007, SECTION 126, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 5. (a) This section applies under the following statutes:

(1) IC 12-26-6.

(2) IC 12-26-7.

(3) IC 12-26-12.

(4) IC 12-26-15.

(b) A petitioner may be represented by counsel.

(c) The court may appoint counsel for a petitioner upon a showing of the petitioner's indigency and the court shall pay for such counsel if appointed.

(d) A petitioner, including a petitioner who is a health care provider under ~~IC 16-18-2-295(b),~~ **IC 16-18-2-295(c),** in the petitioner's individual capacity or as a corporation is not required to be represented by counsel. If a petitioner who is a corporation elects not to be represented by counsel, the individual representing the corporation at the commitment hearing must present the court with written authorization from:

(1) an officer;

(2) a director;

(3) a principal; or

(4) a manager;

of the corporation that authorizes the individual to represent the interest of the corporation in the proceedings.

(e) The petitioner is required to prove by clear and convincing evidence that:

(1) the individual is mentally ill and either dangerous or gravely disabled; and

(2) detention or commitment of that individual is appropriate.

SECTION 3. IC 16-18-2-46.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 46.5. "Canadian supplier", for purposes of IC 16-47-3, has the meaning set forth in IC 16-47-3-1.**

SECTION 4. IC 16-18-2-88.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 88.3. "Covered individual", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-1.**

SECTION 5. IC 16-18-2-148.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 148.7. "Good faith estimate", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-2.**

SECTION 6. IC 16-18-2-163.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 163.6. "Health care services", for purposes of IC 16-51-1, has the meaning set forth in IC 16-51-1-1.**

SECTION 7. IC 16-18-2-163.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 163.8. "Health carrier", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-3.**

SECTION 8. IC 16-18-2-190.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 190.5. "In network", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-4.**

SECTION 9. IC 16-18-2-216 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 216. (a) "Manufacturer", for purposes of IC 16-42-19 and IC 16-42-21, means a person who by compounding, cultivating, harvesting, mixing, or other process produces or prepares legend drugs. The term includes a person who:

(1) prepares legend drugs in dosage forms by mixing,

compounding, encapsulating, entableting, or other process; or

(2) packages or repackages legend drugs.

(b) The term does not include pharmacists or practitioners (as defined in section ~~288(a)~~ **288(b)** and ~~288(c)~~ **288(d)** of this chapter) in the practice of their profession.

SECTION 10. IC 16-18-2-247.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 247.5. "Network", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-5.**

SECTION 11. IC 16-18-2-247.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 247.6. "Network plan", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-6.**

SECTION 12. IC 16-18-2-250.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 250.5. "Nonemergency health care service", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-7.**

SECTION 13. IC 16-18-2-254.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 254.4. "Off-campus location of a hospital", for purposes of IC 16-21-16, has the meaning set forth in IC 16-21-16-3.**

SECTION 14. IC 16-18-2-288, AS AMENDED BY P.L.96-2014, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 288. **(a) "Practitioner", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-8.**

~~(a)~~ **(b)** "Practitioner", for purposes of IC 16-42-19, has the meaning set forth in IC 16-42-19-5.

~~(b)~~ **(c)** "Practitioner", for purposes of IC 16-41-14, has the meaning set forth in IC 16-41-14-4.

~~(c)~~ **(d)** "Practitioner", for purposes of IC 16-42-21, has the meaning set forth in IC 16-42-21-3.

~~(d)~~ **(e)** "Practitioner", for purposes of IC 16-42-22 and IC 16-42-25, has the meaning set forth in IC 16-42-22-4.5.

(f) "Practitioner", for purposes of IC 16-51-1, has the meaning set forth in IC 16-51-1-4.

SECTION 15. IC 16-18-2-294.5, AS AMENDED BY P.L.208-2015, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 294.5. (a) "Program", for purposes of IC 16-40-4, has the meaning set forth in IC 16-40-4-3.

(b) "Program", for purposes of IC 16-41-7.5, has the meaning set forth in IC 16-41-7.5-2.

(c) "Program", for purposes of IC 16-47-1, has the meaning set forth in IC 16-47-1-3.

(d) "Program", for purposes of IC 16-47-3, has the meaning set forth in IC 16-47-3-2.

SECTION 16. IC 16-18-2-295, AS AMENDED BY P.L.161-2014, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 295. (a) "Provider", for purposes of IC 16-21-8, has the meaning set forth in IC 16-21-8-0.2.

(b) "Provider", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-9.

~~(b)~~ **(c)** "Provider", for purposes of IC 16-38-5, IC 16-39 (except for IC 16-39-7), and IC 16-41-1 through IC 16-41-9, means any of the following:

(1) An individual (other than an individual who is an employee or a contractor of a hospital, a facility, or an agency described in subdivision (2) or (3)) who is licensed, registered, or certified as a health care professional, including the following:

(A) A physician.

(B) A psychotherapist.

(C) A dentist.

(D) A registered nurse.

(E) A licensed practical nurse.

(F) An optometrist.

(G) A podiatrist.

(H) A chiropractor.

(I) A physical therapist.

(J) A psychologist.

(K) An audiologist.

(L) A speech-language pathologist.

(M) A dietitian.

(N) An occupational therapist.

(O) A respiratory therapist.

(P) A pharmacist.

(Q) A sexual assault nurse examiner.

(2) A hospital or facility licensed under IC 16-21-2 or IC 12-25 or described in IC 12-24-1 or IC 12-29.

(3) A health facility licensed under IC 16-28-2.

(4) A home health agency licensed under IC 16-27-1.

(5) An employer of a certified emergency medical technician, a certified advanced emergency medical technician, or a licensed

paramedic.

(6) The state department or a local health department or an employee, agent, designee, or contractor of the state department or local health department.

~~(c)~~ **(d)** "Provider", for purposes of IC 16-39-7-1, has the meaning set forth in IC 16-39-7-1(a).

~~(d)~~ **(e)** "Provider", for purposes of IC 16-48-1, has the meaning set forth in IC 16-48-1-3.

SECTION 17. IC 16-18-2-295.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 295.5. "Provider facility", for purposes of IC 16-21-15, has the meaning set forth in IC 16-21-15-10.**

SECTION 18. IC 16-18-2-328.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 328.7. "Service facility location", for purposes of IC 16-51-1, has the meaning set forth in IC 16-51-1-6.**

SECTION 19. IC 16-18-2-353.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 353.3. "Track-and-trace", for purposes of IC 16-47-3, has the meaning set forth in IC 16-47-3-3.**

SECTION 20. IC 16-18-2-362.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 362.1. "Urgent care facility", for purposes of IC 16-24.5-1, has the meaning set forth in IC 16-24.5-1-1.**

SECTION 21. IC 16-18-2-363.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 363.5. "Vendor", for purposes of IC 16-47-3, has the meaning set forth in IC 16-47-3-4.**

SECTION 22. IC 16-21-3-2, AS AMENDED BY P.L.197-2011, SECTION 61, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 2. **(a)** The state health commissioner may take action under section 1 of this chapter on any of the following grounds:

(1) Violation of any of the provisions of this chapter or of the rules adopted under this chapter.

(2) Permitting, aiding, or abetting the commission of any illegal act in an institution.

(3) Knowingly collecting or attempting to collect from a subscriber (as defined in IC 27-13-1-32) or an enrollee (as defined in IC 27-13-1-12) of a health maintenance organization (as

defined in IC 27-13-1-19) any amounts that are owed by the health maintenance organization.

(4) Conduct or practice found by the state department to be detrimental to the welfare of the patients of an institution.

(b) The state health commissioner may take action:

(1) under section 1(1) or 1(2) of this chapter for an initial violation or isolated violations of IC 16-21-15; or

(2) under section 1(4) or 1(5) of this chapter for repeated or persistent violations of IC 16-21-15;

concerning the providing of a good faith estimate within three (3) business days to an individual for whom a nonemergency health care service has been ordered.

SECTION 23. IC 16-21-15 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 15. Provider Facility Good Faith Estimates

Sec. 0.5. Nothing in this chapter prohibits:

(1) a self-funded health benefit plan that complies with the federal Employee Retirement Income Security Act (ERISA) of 1974 (29 U.S.C. 1001 et seq.); or

(2) a self-insurance program established to provide group health coverage as described in IC 5-10-8-7(b), or a contract for health services as described in IC 5-10-8-7(c);

from providing information requested by a practitioner or provider facility under this chapter.

Sec. 1. As used in this chapter, "covered individual" means an individual who is entitled to be provided health care services according to a health carrier's network plan.

Sec. 2. As used in this chapter, "good faith estimate" means a reasonable estimate of the total price a provider anticipates charging for one (1) or more nonemergency health care services that:

(1) is made by a provider under this chapter upon the request of the individual for whom the nonemergency health care service has been ordered; and

(2) is not binding upon the provider.

Sec. 3. (a) As used in this chapter, "health carrier" means an entity:

(1) that is subject to IC 27 and the administrative rules adopted under IC 27; and

(2) that enters into a contract to:

(A) provide health care services;

(B) deliver health care services;

(C) arrange for health care services; or

(D) pay for or reimburse any of the costs of health care services.

(b) The term includes the following:

(1) An insurer, as defined in IC 27-1-2-3(x), that issues a policy of accident and sickness insurance, as defined in IC 27-8-5-1(a).

(2) A health maintenance organization, as defined in IC 27-13-1-19.

(3) An administrator (as defined in IC 27-1-25-1(a)) that is licensed under IC 27-1-25.

(4) Any other entity that provides a plan of health insurance, health benefits, or health care services.

Sec. 4. As used in this chapter, "in network", when used in reference to a provider, means that the health care services provided by the provider are subject to a health carrier's network plan.

Sec. 5. (a) As used in this chapter, "network" means a group of provider facilities and practitioners that:

(1) provide health care services to covered individuals; and

(2) have agreed to, or are otherwise subject to, maximum limits on the fees and charges for the health care services to be provided to the covered individuals.

(b) The term includes the following:

(1) A network described in subsection (a) that is established pursuant to a contract between an insurer providing coverage under a group health policy and:

(A) individual provider facilities and practitioners;

(B) a preferred provider organization; or

(C) an entity that employs or represents providers, including:

(i) an independent practice association; and

(ii) a physician-hospital organization.

(2) A health management organization, as defined in IC 27-13-1-19.

Sec. 6. As used in this chapter, "network plan" means a plan of a health carrier that:

(1) requires a covered person to receive; or

(2) creates incentives, including financial incentives, for a covered person to receive;

health care services from one (1) or more providers that are under

contract with, managed by, or owned by the health carrier.

Sec. 7. (a) As used in this chapter, "nonemergency health care service" means a service or series of services ordered, scheduled, or referred by a practitioner for the purpose of:

(1) diagnosis;

(2) prevention;

(3) treatment;

(4) cure; or

(5) relief;

of a physical, mental, or behavioral health condition, illness, injury, or disease that is not provided on an emergency basis.

Sec. 8. As used in this chapter, "practitioner" means:

(1) an individual who holds a license, certificate, registration, or permit under:

(A) IC 25-22.5 (physicians);

(B) IC 25-27 (physical therapists); or

(C) IC 25-33 (psychologists); or

(2) an organization consisting of or employing two (2) or more individuals described in subdivision (1).

Sec. 8.5. As used in this chapter, "price" means the negotiated rate between the:

(1) provider facility and practitioner; and

(2) covered individual's health carrier.

Sec. 9. As used in this chapter, "provider" means:

(1) a provider facility; or

(2) a practitioner.

Sec. 10. As used in this chapter, "provider facility"means any of the following:

(1) A hospital licensed under IC 16-21-2.

(2) An ambulatory outpatient surgery center licensed under IC 16-21-2.

(3) An abortion clinic licensed under IC 16-21-2.

(4) A birthing center licensed under IC 16-21-2.

(5) A facility that provides diagnostic services to the medical profession or the general public, including outpatient facilities.

(6) A laboratory where clinical pathology tests are carried out on specimens to obtain information about the health of a patient.

(7) A facility where radiologic and electromagnetic images are made to obtain information about the health of a patient.

(8) An infusion center that administers intravenous

medications.

Sec. 11. (a) This section does not:

(1) apply to a individual who is a Medicaid recipient; or

(2) limit the authority of a legal representative of the patient.

(b) An individual for whom a nonemergency health care service has been ordered may request from the provider facility in which the health care service will be provided a good faith estimate of the total price that will be charged as a result of the nonemergency health care service.

(c) A provider facility that receives a request from an individual under subsection (b) shall, not more than three (3) business days after receiving the request, provide to the individual a good faith estimate of:

(1) the total price that the provider facility in which the health care service will be performed will impose for:

(A) the use of the provider facility to care for the individual before, during, and after the nonemergency health care service;

(B) the services rendered by the staff of the provider facility in connection with the nonemergency health care service; and

(C) medication, supplies, equipment, and material items to be provided to or used by the individual while the individual is present in the provider facility in connection with the nonemergency health care service; and

(2) fees charged for the services of all practitioners, support staff, and other persons who provide professional health services:

(A) who will provide services to or for the individual during the individual's presence in the provider facility for the nonemergency health care service; and

(B) for whose services the individual will be charged separately from the charge of the provider facility.

(d) The charges that must be included in a good faith estimate under this section include all charges under subsection (c)(1) or (c)(2) for imaging, laboratory services, diagnostic services, therapy, observation services, and other services expected to be provided to the individual.

(e) A provider facility must ensure that a good faith estimate provided to an individual under this section is accompanied by a notice stating that:

(1) an estimate provided under this section is not binding on

the provider facility; and

(2) the price the provider facility charges the individual may vary from the estimate based on the individual's medical needs.

(f) A provider facility may not charge a patient for information provided under this section.

Sec. 12. (a) If:

(1) the individual who requests a good faith estimate from a provider facility under this chapter and has been verified as a covered individual with respect to a network plan; and

(2) the provider facility from which the individual requests the good faith estimate is in network with respect to the same network plan;

the good faith estimate that the provider facility provides to the individual under this chapter must be based on the negotiated charges to which the provider facility and any practitioners referred to in section 11(c)(2) of this chapter have agreed as in network providers.

(b) If the individual who requests a good faith estimate from a provider facility under this chapter:

(1) is not a covered individual with respect to any network plan; or

(2) is not a covered individual with respect to a network plan with respect to which the provider facility is in network;

the good faith estimate that the provider facility provides to the individual under this chapter must be based on the amounts that the provider facility and any practitioners referred to in section 11(c)(2) of this chapter charge for the nonemergency health care services in the absence of any network plan.

Sec. 13. A provider facility may provide a good faith estimate to an individual under this chapter:

(1) in a writing delivered to the individual;

(2) by electronic mail; or

(3) through a mobile application;

according to the preference expressed by the individual.

Sec. 14. (a) A good faith estimate provided by a provider facility to an individual under this chapter must:

(1) state the services and material items that the good faith estimate is based on;

(2) set forth the estimated price for the services and material items referred to in subdivision (1); and

(3) include a total figure that is a sum of the estimated prices

referred to in subdivision (2).

(b) Subsection (a) does not prohibit a provider facility from providing to an individual a good faith estimate that indicates how much of the total figure stated under subsection (a)(3) will be the individual's out-of-pocket expense after the health carrier's payment of charges.

(c) A health carrier must provide a provider facility with timely information needed by the provider facility to comply with the requirements under this chapter.

Sec. 15. (a) As used in this section, "waiting room" means a space in a building used by a provider facility in which people check in or register to:

(1) be seen by practitioners; or

(2) meet with members of the staff of the provider facility.

(b) A provider facility shall ensure that each waiting room of the provider facility includes at least one (1) printed notice that:

(1) is designed, lettered, and positioned within the waiting room so as to be conspicuous to and readable by any individual with normal vision who visits the waiting room; and

(2) states the following, or words to the same effect: "A patient may ask for an estimate of the amount the patient will be charged for a nonemergency medical service provided in this facility. The law requires that an estimate be provided within 3 business days.".

(c) If a provider facility maintains an Internet web site, the provider facility shall ensure that the Internet web site includes at least one (1) printed notice that:

(1) is designed, lettered, and featured on the Internet web site so as to be conspicuous to and readable by any individual with normal vision who visits the Internet web site; and

(2) states the following, or words to the same effect: "A patient may ask for an estimate of the amount the patient will be charged for a nonemergency medical service provided in our facility. The law requires that an estimate be provided within 3 business days.".

SECTION 24. IC 16-21-17 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 17. Health Care Pricing Information

Sec. 1. (a) Not later than March 31, 2021, a hospital and an ambulatory surgical center shall post on the Internet web site of

the hospital or ambulatory outpatient surgical center pricing and other information specified in this chapter for the following:

(1) For as many of the seventy (70) shoppable services specified in 45 CFR 180 (as published August 9, 2019, and as subsequently amended) that are provided by the hospital or ambulatory outpatient surgical center.

(2) In addition to the services specified in subdivision (1), the thirty (30) most common services that are provided by the hospital or ambulatory outpatient surgical center.

(b) The following information must be included on the Internet web site by a hospital and an ambulatory outpatient surgical center for each billing code, including, if relevant, each diagnosis related group (DRG) billing code and each health care common procedure coding system (HCPCS) billing code:

(1) The number of services provided for the code.

(2) A description of the service.

(3) The weighted average prices paid per service per provider type for each of the following categories:

(A) Employer sponsored insurance.

(B) Individually purchased insurance.

(C) Medicare, including fee for service and Medicare Advantage.

(D) Self pay without charitable assistance from the hospital or ambulatory surgical center.

(E) Self pay with charitable assistance from the hospital or ambulatory surgical center.

Sec. 2. (a) The information displayed on the Internet web site must be in an easy to read, understandable format, and include the prices for each billing code by provider type.

(b) A hospital and an ambulatory outpatient surgical center shall update the information on the Internet web site on a quarterly basis.

SECTION 25. IC 16-24.5 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

ARTICLE 24.5. OTHER HEALTH CARE FACILITIES

Chapter 1. Urgent Care Facilities

Sec. 1. (a) As used in this chapter, "urgent care facility" means a free standing health care facility that offers episodic, walk-in care for the treatment of acute, but not life-threatening, health conditions.

(b) The term does not include an emergency department of a

hospital or a nonprofit or government operated health clinic.

Sec. 2. (a) Not later than March 31, 2021, an urgent care facility shall post on the Internet web site of the urgent care facility pricing and other information specified in this chapter for the fifteen (15) most common services that are provided by the urgent care facility.

(b) The following information must be included on the Internet web site by an urgent care facility for each billing code, including, if relevant, each diagnosis related group (DRG) billing code and each health care common procedure coding system (HCPCS) billing code:

(1) The number of services provided for the code.

(2) A description of the service.

(3) The weighted average prices paid per service per provider type for each of the following categories:

(A) Employer sponsored insurance.

(B) Individually purchased insurance.

(C) Medicare, including fee for service and Medicare Advantage.

(D) Self pay without charitable assistance from the hospital or ambulatory surgical center.

(E) Self pay with charitable assistance from the hospital or ambulatory surgical center.

Sec. 3. (a) The information displayed on the Internet web site must be in an easy to read, understandable format, and include the prices for each billing code by provider type.

(b) An urgent care facility shall update the information on the Internet web site on a quarterly basis.

SECTION 26. IC 16-47-3 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 3. Importation of Prescription Drugs Program

Sec. 1. As used in this chapter, "Canadian supplier" means a:

(1) manufacturer;

(2) wholesale drug distributor; or

(3) pharmacy;

appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

Sec. 2. As used in this chapter, "program" refers to the importation of prescription drugs program established by section 5 of this chapter.

Sec. 3. As used in this chapter, "track-and-trace" means the

product-tracing process for the components of the pharmaceutical distribution supply chain, as described in Title II of the federal Drug Quality and Security Act (21 U.S.C. 351 et seq.).

Sec. 4. As used in this chapter, "vendor" means an entity that contracts with the state department to manage specified functions of the program.

Sec. 5. (a) The importation of prescription drugs program is established.

(b) The state department shall administer the program.

(c) The state department shall contract with a vendor to provide services under the program. The vendor must comply with the requirements of this chapter.

(d) The state department shall require a bond from the vendor to mitigate the financial consequences of potential acts of malfeasance or misfeasance, potential fraudulent acts, or potential dishonest acts committed by the vendor, an employee of the vendor, or a contractor or subcontractor of the vendor.

(e) Before July 1, 2021, the state department shall apply to the United States Department of Health and Human Services for approval of the program under 21 U.S.C. 384(1). The state department shall implement the program not later than six (6) months after the state department receives approval for the program. The request must include the following:

(1) A description of the state department's plan for operating the program.

(2) A demonstration of how the prescription drugs imported into Indiana under the program will meet the applicable federal and state standards for safety and effectiveness.

(3) A demonstration of how the prescription drugs imported into Indiana under the program will comply with federal track-and-trace procedures.

(4) A list of proposed prescription drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted.

(5) An estimate of the total cost savings attributable to the program.

(6) The costs of program implementation to the state.

(7) A list of potential Canadian suppliers from which the state would import the prescription drugs and a demonstration that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations, as well as all applicable federal and state laws and regulations.

(f) Upon receipt of federal approval of the program, the state department shall notify the following:

(1) The speaker of the house of representatives.

(2) The president pro tempore of the senate.

(3) The members of the health and provider services committee in the senate.

(4) The members of the public health committee in the house of representatives.

(g) Before the start of the general assembly session following receipt of the federal approval, the state department shall submit to the individuals described in subsection (f) a proposal for the implementation of funding of the program.

Sec. 6. (a) Before December 1, 2020, and by December 1 of each subsequent year, the vendor shall develop a wholesale prescription drug importation list identifying the prescription drugs that have the highest potential for cost savings to the state.

(b) In developing the list, the vendor shall consider at least the following in determining whether a prescription drug should be included on the list:

(1) Prescription drugs that, if included on the list, would provide the highest potential for cost savings in state administered programs.

(2) Prescription drugs for which there is a shortage in Indiana or the United States.

(3) Specialty prescription drugs.

(4) High volume prescription drugs.

(c) The state department shall review the wholesale prescription drug importation list at least every three (3) months to ensure that the list continues to meet the requirements of the program. The state department may direct the vendor to revise the list as necessary.

Sec. 7. (a) The vendor shall identify Canadian suppliers that:

(1) are in full compliance with:

(A) relevant Canadian federal and provincial laws and regulations; and

(B) the federal Drug Quality and Security Act;

(2) have agreed to export prescription drugs identified on the list described in section 6 of this chapter at prices that will provide cost savings to the state; and

(3) have obtained an international export pharmacy permit under IC 25-26-14.5.

(b) The vendor must verify that the Canadian suppliers meet all

of the requirements of the program while meeting or exceeding the federal and state track-and-trace laws and regulations.

(c) The vendor shall:

(1) contract with an eligible Canadian supplier; or

(2) facilitate contracts between eligible importers and Canadian suppliers;

to import drugs under the program.

(d) The vendor shall maintain a list of all registered importers that participate in the program.

(e) The vendor shall ensure compliance with Title II of the federal Drug Quality and Security Act by all suppliers, importers, distributors, and participants in the program.

Sec. 8. (a) The vendor shall provide to the state department the following:

(1) An annual financial audit of the vendor's operations.

(2) Quarterly financial reports specific to the program, including information on the performance of the vendor and the vendor's subcontractors for the program.

(b) The state department shall determine the format and contents of the reports described in this section.

Sec. 9. (a) A Canadian supplier is eligible to participate in the program if the Canadian supplier meets the following requirements:

(1) Is in full compliance with relevant Canadian federal and provincial laws and regulations.

(2) Is identified by the vendor as eligible to participate in the program.

(3) Submits an attestation that the supplier has a registered agent in the United States, including the name and United States business address of the registered agent.

(b) An importer that meets the requirements of this chapter may import a prescription drug from an eligible Canadian supplier if the following conditions are met:

(1) The prescription drug meets the United States Food and Drug Administration's standards concerning safety, effectiveness, misbranding, and adulteration.

(2) The importation of the drug would not violate federal patent laws.

(3) The importation of the drug is expected to generate cost savings to the state.

(4) The drug is not any of the following:

(A) A controlled substance.

(B) A biological product.

(C) An infused drug.

(D) An intravenously injected drug.

(E) A drug that is inhaled during surgery.

(F) A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

Sec. 10. (a) The following entities may import prescription drugs under the program from a Canadian supplier that meets the requirements of this chapter:

(1) A pharmacist or wholesale drug distributor employed by or under contract with the state department for distribution to a county health department for dispensing to the patients of the county health department.

(2) A pharmacist or wholesale drug distributor employed by or under contract with a pharmacy that is a Medicaid provider, for dispensing to the pharmacy's Medicaid recipients.

(3) A pharmacist or wholesale drug distributor employed by or under contract with the department of correction, for dispensing to inmates in the custody of the department of correction.

(b) A Canadian supplier that meets the requirements of this chapter and an eligible importer described in subsection (a) that is participating in the program:

(1) must comply with all track-and-trace requirements; and

(2) may not distribute, dispense, or sell prescription drugs imported under this program outside Indiana.

Sec. 11. (a) The vendor shall ensure the safety and quality of drugs imported under the program.

(b) The vendor shall do the following:

(1) For an initial imported shipment of a specific drug by an importer, ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with federal law.

(2) For every subsequent imported shipment of that drug by that importer, ensure that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with federal law.

(3) Certify that the drug:

(A) is approved for marketing in the United States and is

not adulterated or misbranded; and

(B) meets all of the labeling requirements under 21 U.S.C. 352.

(4) Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

(5) Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with federal and state laws and regulations governing laboratory qualifications.

(c) All testing required by this section must be conducted in a qualified laboratory that meets the standards under federal and state laws and regulations governing laboratory qualifications for drug testing.

(d) The vendor shall maintain information and documentation submitted under this section for at least seven (7) years.

Sec. 12. An importer participating in the program must submit all of the following information to the vendor concerning drugs provided for the program:

(1) The name and quantity of the active ingredients of the drug.

(2) A description of the dosage form of the drug.

(3) The date on which the drug is received.

(4) The quantity of the drug that is received.

(5) The point of origin and destination of the drug.

(6) The price paid by the importer for the drug.

Sec. 13. (a) A Canadian supplier participating in the program must submit the following information and documentation to the vendor specifying all of the following concerning drugs provided for the program:

(1) The original source of the drug, including:

(A) the name of the manufacturer of the drug;

(B) the date on which the drug was manufactured; and

(C) the location, including the country, state or province, and city, where the drug was manufactured.

(2) The date on which the drug is shipped.

(3) The quantity of the drug that is shipped.

(4) The quantity of each lot of the drug originally received and the source of the lot.

(5) The lot or control number and the batch number assigned to the drug by the manufacturer.

(b) The state department may require that the vendor collect

additional information from the Canadian supplier that is necessary to ensure the protection of the public health.

Sec. 14. (a) The state department shall immediately suspend the importation of a specific drug or the importation of drugs by a specific importer if the state department discovers that any drug or importer activity is in violation of this chapter or any federal or state law or regulation.

(b) The state department may revoke the suspension under subsection (a) of the importation of a specific drug or the importation of drugs by a specific importer if the state department determines that the public is adequately protected from counterfeit or unsafe drugs being imported into Indiana.

Sec. 15. Before December 1 of each year, the state department shall submit a report to the governor and the general assembly in an electronic format under IC 5-14-6 on the operation of the program during the previous fiscal year. The report must include at least the following:

(1) A list of the prescription drugs that were imported under the program.

(2) The number of participating persons.

(3) The number of prescriptions dispensed through the program.

(4) The estimated cost savings to the state during the previous fiscal year and to date that are attributable to the program.

(5) A description of the methodology used to determine which drugs should be included on the wholesale prescription drug importation list.

(6) Documentation on how the program ensures the following:

(A) Canadian suppliers participating in the program are of high quality and high performance and in full compliance with relevant:

(i) Canadian federal and provincial laws and regulations; and

(ii) federal and state laws, regulations, and rules.

(B) Prescription drugs imported under the program are not shipped, sold, or dispensed outside Indiana once in the possession of the importer.

(C) Prescription drugs imported under the program are pure, unadulterated, potent, and safe.

(D) The program does not place consumers at a higher health and safety risk than if the consumers did not participate.

(E) The program provides cost savings to the state on imported prescription drugs.

Sec. 16. The state department shall adopt rules under IC 4-22-2 necessary to implement this chapter.

SECTION 27. IC 16-51 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

ARTICLE 51. HEALTH CARE REQUIREMENTS

Chapter 1. Health Care Billing

Sec. 1. (a) As used in this chapter, "health care services" means health care related services or products rendered or sold by a provider within the scope of the provider's license or legal authorization.

(b) The term includes hospital, medical, surgical, dental, vision, and pharmaceutical services or products.

Sec. 2. As used in this chapter, "health maintenance organization" has the meaning set forth in IC 27-13-1-19.

Sec. 3. As used in this chapter, "insurer" has the meaning set forth in IC 27-8-11-1(e).

Sec. 4. As used in this chapter, "practitioner" means an individual or entity duly licensed or legally authorized to provide health care services.

Sec. 5. As used in this chapter, "provider facility" means any of the following:

(1) A hospital.

(2) A skilled nursing facility.

(3) An end stage renal disease provider.

(4) A home health agency.

(5) A hospice organization.

(6) An outpatient physical therapy, occupational therapy, or speech pathology service provider.

(7) A comprehensive outpatient rehabilitation facility.

(8) A community mental health center.

(9) A critical access hospital.

(10) A federally qualified health center.

(11) A histocompatibility laboratory.

(12) An Indian health service facility.

(13) An organ procurement organization.

(14) A religious nonmedical health care institution.

(15) A rural health clinic.

Sec. 6. As used in this chapter, "service facility location" means the address where the services of a provider facility or practitioner

were provided. The term consists of exact address and place of service codes as required on CMS forms 1500 and 1450, including an office, on-campus location of a hospital, and off-campus location of a hospital.

Sec. 7. (a) A provider facility or practitioner shall include the address of the service facility location in order to obtain reimbursement for a commercial claim for health care services from an insurer, health maintenance organization, employer, or other person responsible for the payment of the cost of health care services.

(b) An insurer, health maintenance organization, employer, or other person responsible for the payment of the cost of health care services is not required to accept a bill for health care services that does not contain the service facility location.

Sec. 8. A patient is not liable for any additional payment that is the result of a practitioner or provider facility filing an incorrect form or not including the correct service facility location as required under this chapter.

SECTION 28. IC 25-22.5-16 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 16. Practitioner Good Faith Estimates

Sec. 1. As used in this chapter, "covered individual" means an individual who is entitled to be provided health care services according to a health carrier's network plan.

Sec. 2. As used in this chapter, "good faith estimate" means a reasonable estimate of the total price a practitioner anticipates charging for one (1) or more nonemergency health care services that:

(1) is made by a practitioner under this chapter upon the request of:

(A) the individual for whom the nonemergency health care service has been ordered; or

(B) the provider facility in which the nonemergency health care service will be provided; and

(2) is not binding upon the practitioner.

Sec. 3. (a) As used in this chapter, "health carrier" means an entity:

(1) that is subject to IC 27 and the administrative rules adopted under IC 27; and

(2) that enters into a contract to:

(A) provide health care services;

(B) deliver health care services;

(C) arrange for health care services; or

(D) pay for or reimburse any of the costs of health care services.

(b) The term includes the following:

(1) An insurer, as defined in IC 27-1-2-3(x), that issues a policy of accident and sickness insurance, as defined in IC 27-8-5-1(a).

(2) A health maintenance organization, as defined in IC 27-13-1-19.

(3) An administrator (as defined in IC 27-1-25-1(a)) that is licensed under IC 27-1-25.

(4) Any other entity that provides a plan of health insurance, health benefits, or health care services.

Sec. 4. As used in this chapter, "in network", when used in reference to a practitioner, means that the health care services provided by the practitioner are subject to a health carrier's network plan.

Sec. 5. (a) As used in this chapter, "network" means a group of provider facilities and practitioners that:

(1) provide health care services to covered individuals; and

(2) have agreed to, or are otherwise subject to, maximum limits on the fees and charges for the health care services to be provided to the covered individuals.

(b) The term includes the following:

(1) A network described in subsection (a) that is established pursuant to a contract between an insurer providing coverage under a group health policy and:

(A) individual provider facilities and practitioners;

(B) a preferred provider organization; or

(C) an entity that employs or represents providers, including:

(i) an independent practice association; and

(ii) a physician-hospital organization.

(2) A health management organization, as defined in IC 27-13-1-19.

Sec. 6. As used in this chapter, "network plan" means a plan of a health carrier that:

(1) requires a covered person to receive; or

(2) creates incentives, including financial incentives, for a covered person to receive;

health care services from one (1) or more providers that are under

contract with, managed by, or owned by the health carrier.

Sec. 7. (a) As used in this chapter, "nonemergency health care service" means a service or series of services ordered, scheduled, or referred by a practitioner for the:

(1) diagnosis;

(2) prevention;

(3) treatment;

(4) cure; or

(5) relief;

of a physical, mental, or behavioral health condition, illness, injury, or disease that is not provided on an emergency basis.

Sec. 8. As used in this chapter, "practitioner" means:

(1) an individual who holds a license, certificate, registration, or permit under:

(A) IC 25-22.5 (physicians);

(B) IC 25-27 (physical therapists); or

(C) IC 25-33 (psychologists); or

(2) an organization consisting of or employing two (2) or more individuals described in subdivision (1).

Sec. 8.5. As used in this chapter, "price" means the negotiated rate between the:

(1) provider facility and practitioner; and

(2) covered individual's health carrier.

Sec. 9. As used in this chapter, "provider" means:

(1) a provider facility; or

(2) a practitioner.

Sec. 10. As used in this chapter, "provider facility"means any of the following:

(1) A hospital licensed under IC 16-21-2.

(2) An ambulatory outpatient surgery center licensed under IC 16-21-2.

(3) An abortion clinic licensed under IC 16-21-2.

(4) A birthing center licensed under IC 16-21-2.

(5) A facility that provides diagnostic services to the medical profession or the general public.

(6) A laboratory where clinical pathology tests are carried out on specimens to obtain information about the health of a patient.

(7) A facility where radiologic and electromagnetic images are made to obtain information about the health of a patient.

(8) An infusion center that administers intravenous medications.

Sec. 11. (a) This section does not apply to a individual who is a Medicaid recipient.

(b) An individual for whom a nonemergency health care service has been ordered may request from the practitioner who will provide the nonemergency health care service a good faith estimate of the total price the practitioner will charge for providing the nonemergency health care service.

(c) A practitioner who receives a request from a patient under subsection (b) shall, not more than three (3) business days after receiving the request, provide to the individual a good faith estimate of the total price that the practitioner will charge for providing the nonemergency health care service.

(d) A practitioner must ensure that a good faith estimate provided to an individual under this section is accompanied by a notice stating that:

(1) an estimate provided under this section is not binding on the practitioner; and

(2) the amount the practitioner charges the individual may vary from the estimate based on the individual's medical needs.

(e) A practitioner may not charge an individual for information provided under this section.

Sec. 12. (a) If:

(1) the individual who requests a good faith estimate from a practitioner under this chapter is a covered individual with respect to a network plan; and

(2) the practitioner from which the individual requests the good faith estimate is in network with respect to the same network plan;

the good faith estimate that the practitioner provides to the individual under this chapter must be based on the negotiated charges to which the practitioner has agreed as an in network provider.

(b) If the individual who requests a good faith estimate from a practitioner under this chapter:

(1) is not a covered individual with respect to any network plan; or

(2) is not a covered individual with respect to a network plan with respect to which the practitioner is in network;

the good faith estimate that the practitioner provides to the individual under this chapter must be based on the amounts that the practitioner charges for the nonemergency health care service

in the absence of any network plan.

Sec. 13. A practitioner may provide a good faith estimate to an individual under this chapter:

(1) in a writing delivered to the individual;

(2) by electronic mail; or

(3) through a mobile application;

according to the preference expressed by the individual.

Sec. 14. (a) A good faith estimate provided by a practitioner to an individual under this chapter must:

(1) state the services and material items that the good faith estimate is based on;

(2) set forth the estimated price for the services and material items referred to in subdivision (1); and

(3) include a total figure that is a sum of the estimated prices referred to in subdivision (2).

(b) Subsection (a) does not prohibit a practitioner from providing to an individual a good faith estimate that indicates how much of the total figure stated under subsection (a)(3) will be the individual's out-of-pocket expense after the health carrier's payment of charges.

(c) A health carrier must provide a practitioner with timely information needed by the practitioner to comply with the requirements under this chapter.

Sec. 15. If:

(1) a practitioner is expected to provide a nonemergency health care service to an individual in a provider facility; and

(2) the provider facility receives a request from an individual for a good faith estimate under IC 16-21-15;

the practitioner, upon request from the provider facility, shall provide to the provider facility a good faith estimate of the practitioner's charge for providing the nonemergency health care service to enable the provider facility to comply with IC 16-21-15-11.

Sec. 16. (a) A practitioner that has ordered, scheduled, or referred the individual for a nonemergency health care service shall provide to the individual an electronic or paper copy of a written notice that states the following, or words to the same effect: "A patient may at any time ask a practitioner for an estimate of the amount the practitioner will charge for providing a nonemergency medical service. The law requires that the estimate be provided within 3 business days.".

(b) The state department may adopt rules under IC 4-22-2 to

establish requirements for practitioners to provide additional charging information under this section.

Sec. 17. The appropriate board (as defined in IC 25-1-9-1) may take action against a practitioner:

(1) under IC 25-1-9-9(a)(3) or IC 25-1-9-9(a)(4) for an initial violation or isolated violations of this chapter; or

(2) under IC 25-1-9-9(a)(1), IC 25-1-9-9(a)(2), or IC 25-1-9-9(a)(6) for repeated or persistent violations of this chapter;

concerning the providing of a good faith estimate to an individual for whom a nonemergency health care service has been ordered or the providing of notice in the practitioner's office or on the practitioner's Internet web site that a patient may at any time ask for an estimate of the amount that the patient will be charged for a medical service.

SECTION 29. IC 25-26-13-4, AS AMENDED BY P.L.5-2016, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 4. (a) The board may:

(1) adopt rules under IC 4-22-2 for implementing and enforcing this chapter;

(2) establish requirements and tests to determine the moral, physical, intellectual, educational, scientific, technical, and professional qualifications for applicants for pharmacists' licenses;

(3) refuse to issue, deny, suspend, or revoke a license or permit or place on probation or fine any licensee or permittee under this chapter;

(4) regulate the sale of drugs and devices in the state of Indiana;

(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or their representatives from entering such places and making such inspections;

(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;

(7) subject to IC 25-1-7, investigate complaints, subpoena

witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;

(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; and

(9) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter.

(b) The board shall adopt rules under IC 4-22-2 for the following:

(1) Establishing standards for the competent practice of pharmacy.

(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.

(3) Establishing standards and procedures before January 1, 2006, to ensure that a pharmacist:

(A) has entered into a contract that accepts the return of expired drugs with; or

(B) is subject to a policy that accepts the return of expired drugs of;

a wholesaler, manufacturer, or agent of a wholesaler or manufacturer concerning the return by the pharmacist to the wholesaler, the manufacturer, or the agent of expired legend drugs or controlled drugs. In determining the standards and procedures, the board may not interfere with negotiated terms related to cost, expenses, or reimbursement charges contained in contracts between parties, but may consider what is a reasonable quantity of a drug to be purchased by a pharmacy. The standards and procedures do not apply to vaccines that prevent influenza, medicine used for the treatment of malignant hyperthermia, and other drugs determined by the board to not be subject to a return policy. An agent of a wholesaler or manufacturer must be appointed in writing and have policies, personnel, and facilities to handle properly returns of expired legend drugs and controlled substances.

(4) The following concerning the issuance of a permit under IC 25-26-14.5:

(A) Inspection report requirements described under IC 25-26-14.5-1.

(B) The financial responsibility of entities that hold any permit under IC 25-26-14.5.

(c) The board may grant or deny a temporary variance to a rule it has adopted if:

(1) the board has adopted rules which set forth the procedures and standards governing the grant or denial of a temporary variance; and

(2) the board sets forth in writing the reasons for a grant or denial of a temporary variance.

(d) The board shall adopt rules and procedures, in consultation with the medical licensing board, concerning the electronic transmission of prescriptions. The rules adopted under this subsection must address the following:

(1) Privacy protection for the practitioner and the practitioner's patient.

(2) Security of the electronic transmission.

(3) A process for approving electronic data intermediaries for the electronic transmission of prescriptions.

(4) Use of a practitioner's United States Drug Enforcement Agency registration number.

(5) Protection of the practitioner from identity theft or fraudulent use of the practitioner's prescribing authority.

(e) The governor may direct the board to develop:

(1) a prescription drug program that includes the establishment of criteria to eliminate or significantly reduce prescription fraud; and

(2) a standard format for an official tamper resistant prescription drug form for prescriptions (as defined in IC 16-42-19-7(1)).

The board may adopt rules under IC 4-22-2 necessary to implement this subsection.

(f) The standard format for a prescription drug form described in subsection (e)(2) must include the following:

(1) A counterfeit protection bar code with human readable representation of the data in the bar code.

(2) A thermochromic mark on the front and the back of the prescription that:

(A) is at least one-fourth (1/4) of one (1) inch in height and width; and

(B) changes from blue to clear when exposed to heat.

(g) The board may contract with a supplier to implement and manage the prescription drug program described in subsection (e). The supplier must:

(1) have been audited by a third party auditor using the SAS 70 audit or an equivalent audit for at least the three (3) previous years; and

(2) be audited by a third party auditor using the SAS 70 audit or an equivalent audit throughout the duration of the contract;

in order to be considered to implement and manage the program.

(h) The board shall adopt rules under IC 4-22-2, or emergency rules in the manner provided under IC 4-22-2-37.1 that take effect on July 1, 2016, concerning:

(1) professional determinations made under IC 35-48-4-14.7(d); and

(2) the determination of a relationship on record with the pharmacy under IC 35-48-4-14.7.

(i) The board may:

(1) review professional determinations made by a pharmacist; and

(2) take appropriate disciplinary action against a pharmacist who violates a rule adopted under subsection (h) concerning a professional determination made;

under IC 35-48-4-14.7 concerning the sale of ephedrine and pseudoephedrine.

SECTION 30. IC 25-26-13-29, AS AMENDED BY P.L.209-2018, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 29. (a) It is unlawful:

(1) For any person to display or permit to be displayed, a pharmacy permit in any facility or place of business other than that for which it was issued.

(2) For any person to accept a prescription for filling or compounding at any place or facility for which there is not a valid pharmacy permit.

(3) For any person to operate a pharmacy or to take, assume, exhibit, display, or advertise by any medium, the title "drugs", "prescriptions", "medicine", "drug store", "pharmacy", or "apothecary shop", or any combination of such titles or any other title, symbol, term, or description of like import intended to cause the public to believe that it is a pharmacy unless the person holds a valid pharmacy permit.

(4) For any person to engage or offer to engage in the practice of pharmacy or to hold himself or herself out as a pharmacist without a valid pharmacist's license that is classified as active by the board.

(b) A person who violates a provision of subsection (a) commits a Level 6 felony.

(c) Nothing in this chapter shall apply to, nor in any manner interfere with the business of a general merchant in selling and distributing nonnarcotic, nonprescription medicines or drugs which are prepackaged, fully prepared by the manufacturer for use by the consumer, and labeled in accordance with the requirements of the state

and federal food and drug acts.

(d) This chapter does not apply to, or in any manner interfere with, the business of a manufacturer in selling and delivering a dialysate drug or a device that is necessary for home peritoneal renal dialysis for a patient who has end stage renal disease if all of the following apply:

(1) The dialysate drug or device is approved by the federal Food and Drug Administration under federal law.

(2) The dialysate drug or device is held by the manufacturer, a third party logistics provider, or a wholesale drug distributor in accordance with the requirements of IC 25-26-14.

(3) The dialysate drug or device is delivered in the manufacturer's original, sealed packaging.

(4) The dialysate drug or device is delivered only upon:

(A) receipt of a physician's prescription by a pharmacy that holds a pharmacy permit under this chapter; and

(B) the transmittal of an order from the pharmacy described in clause (A) to the manufacturer, third party logistics provider, or wholesale drug distributor.

(5) The manufacturer, third party logistics provider, or wholesale drug distributor delivers the dialysate drug or device directly to:

(A) the patient or the patient's designee for self-administration of the dialysis therapy; or

(B) a health care provider for administration of the dialysis therapy to the patient.

(e) This chapter does not apply to the purchase of prescription drugs through and in compliance with the importation of prescription drugs program established under IC 16-47-3.

SECTION 31. IC 25-26-14-17.8, AS AMENDED BY P.L.98-2006, SECTION 22, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 17.8. (a) **This section does not apply to purchase of prescription drugs through and in compliance with the importation of prescription drugs program established under IC 16-47-3.** A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required under this section and rules adopted by the board. However, the due diligence requirements of this section do not apply to purchases from an unlicensed wholesale drug distributor that has obtained accreditation through the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors program.

(b) Before the initial purchase of legend drugs from the unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall

obtain the following information from the unlicensed wholesale drug distributor:

(1) A list of states in which the unlicensed wholesale drug distributor is licensed.

(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.

(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.

(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.

(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.

(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.

(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.

(8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.

(9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.

(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.

(11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.

(13) A statement:

(A) as to whether; and

(B) of the identity of each manufacturer for which;

the unlicensed wholesale drug distributor is an authorized distributor.

(c) Before the initial purchase of legend drugs from an unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall:

(1) request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department of all

individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and

(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years after a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs from the unlicensed wholesale drug distributor; and

(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall ensure that the unlicensed wholesale drug distributor maintains a record keeping system that meets the requirements of section 17(3) of this chapter.

(f) If a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor has reason to believe that a legend drug purchased from the unlicensed wholesale drug distributor is misbranded, adulterated, counterfeit, or suspected counterfeit, the licensed wholesale drug distributor shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug for which a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and any electronic mail address of the unlicensed wholesale drug distributor that sold the legend drug.

(h) If a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) and is unable to authenticate each distribution of the legend drug, the licensed wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration within ten (10) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

(l) If a wholesale drug distributor conducts a random authentication under subsection (j) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 32. IC 25-26-14.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 14.5. International Export Pharmacy Permit and Wholesale Drug Distributor Permit

Sec. 1. (a) To participate as an exporter of prescription drugs into Indiana under the importation of prescription drugs program established by IC 16-47-3-5, a pharmacy located outside the United States must meet the following requirements:

(1) Hold an international export pharmacy permit issued under this chapter.

(2) Maintain at all times an active and unencumbered license or permit to operate a pharmacy:

(A) in compliance with the laws and rules of the jurisdiction in which the pharmacy is located and from which the prescription drugs will be exported; and

(B) in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(3) Submit an application for an international export pharmacy permit on a form developed and provided by the board.

(b) An applicant for an international export pharmacy permit must submit the following to the board with the application required under subsection (a)(3):

(1) Proof of an active and unencumbered license or permit to operate a pharmacy in compliance with the laws and rules of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported.

(2) Documentation demonstrating that the country in which the pharmacy operates has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(3) The location, names, and title of all principal corporate officers and the pharmacist who serves as the prescription department manager for prescription drugs exported into Indiana under the importation of prescription drugs program.

(4) A written attestation by an owner or officer of the applicant and by the applicant's prescription drug manager containing the following affirmations:

(A) That the individual has read and understands the laws and rules governing the manufacture, distribution, and dispensing of prescription drugs in Indiana.

(B) That prescription drugs shipped, mailed, or delivered into Indiana:

(i) will meet or exceed Indiana's standards for safety and efficacy; and

(ii) will not have been, and may not be, manufactured or distributed in violation of the laws and rules of the jurisdiction in which the applicant is located and from which the prescription drugs will be exported.

(5) A current inspection report from an inspection conducted by the regulatory or licensing agency of the jurisdiction in

which the applicant is located. The inspection report must reflect compliance with this section. An inspection report is current if the inspection was conducted not earlier than six (6) months before the submission of the application for an initial permit or not earlier than one (1) year for the renewal of a permit.

(c) If an applicant is not able to submit an inspection report that meets the requirements of subsection (b)(5), the board must do one (1) of the following:

(1) Conduct, or contract with a person to conduct, an onsite inspection at the cost of the applicant.

(2) Accept a current inspection report from an entity that:

(A) meets requirements adopted by the board under IC 4-22-2 for entities to perform inspections; and

(B) has been approved by the board.

(3) Accept a current inspection report from the United States Food and Drug Administration conducted under the federal Drug Quality and Security Act.

Sec. 2. To participate as an exporter of prescription drugs into Indiana under the importation of prescription drugs program established by IC 16-47-3, a nonresident prescription drug manufacturer located outside the United States must register with the board and obtain the international export pharmacy permit under this chapter.

Sec. 3. (a) The board shall adopt rules under IC 4-22-2 governing the financial responsibility of a pharmacy that holds a permit under this chapter. The rules must include at least the following:

(1) Financial reporting requirements.

(2) Standards for financial capability to perform the functions governed by the permit.

(3) Requirements for ensuring that the permit holder and the permit holder's contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest acts committed by the permit holder or the permit holder's contractors.

(b) The board shall adopt rules under IC 4-22-2 concerning inspection report requirements described in section 1 of this chapter.

Sec. 4. (a) A wholesale drug distributor located outside the United States must obtain an international prescription drug wholesale drug distributor permit under this chapter to engage in

the wholesale exportation and distribution of prescription drugs in Indiana under the importation of prescription drugs program established by IC 16-47-3-5.

(b) A wholesale drug distributor must meet the following in order to obtain a wholesale drug distributor permit:

(1) Be licensed or permitted to operate in a country with which the United States has:

(A) a current mutual recognition agreement;

(B) a current cooperation agreement;

(C) a current memorandum of understanding; or

(D) another federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(2) Maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with the laws and rules of the jurisdiction in which the wholesale drug distributor operates.

(c) The board shall adopt rules under IC 4-22-2 governing the financial responsibility of a wholesale drug distributor that holds a permit under this chapter. The rules must include at least the following:

(1) Financial reporting requirements.

(2) Standards for financial capability to perform the functions governed by the permit.

(3) Requirements for ensuring that a wholesale drug distributor holding a permit under this chapter and the wholesale drug distributor's contractors are held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest acts committed by the permit holder or the permit holder's contractors.

SECTION 33. IC 27-1-15.6-13.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 13.5. (a) An insurance producer shall disclose to any prospective and current clients on a separate written notification any commission, service fee, brokerage fee, or other valuable consideration, including whether the amount is based on a percentage of total plan premiums or a flat per member fee, concerning:**

(1) a health insurance contract that is signed directly with the insurance producer; or

(2) a health insurance contract signed with a third party administrator or insurer that will compensate the insurance

producer.

(b) A copy of the written notification required under this section must be signed by the client.

SECTION 34. IC 27-1-37-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 7. (a) This section applies to:**

(1) health provider contracts; and

(2) contracts between a provider and a pharmacy benefits manager;

entered into or renewed, including contracts that automatically renew after the expiry date, after June 30, 2020.

(b) A health provider contract may not contain a provision that prohibits the disclosure of health care service claims data to employers providing the coverage. However, any disclosure of claims data must comply with health privacy laws, including the federal Health Insurance Portability and Accountability Act (HIPAA) (P.L. 104-191).

(c) A violation of this section constitutes an unfair or deceptive act or practice in the business of insurance under IC 27-4-1-4.

SECTION 35. IC 27-1-45 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]:

Chapter 45. All Payer Claims Data Base

Sec. 1. As used in this chapter, "data base" refers to the all payer claims data base created under this chapter.

Sec. 2. As used in this chapter, "health payer" includes the following:

(1) Medicare.

(2) Medicaid or a managed care organization (as defined in IC 12-7-2-126.9) that has contracted with Medicaid to provide services to a Medicaid recipient.

(3) An insurer that issues a policy of accident and sickness insurance (as defined in IC 27-8-5-1).

(4) A health maintenance organization (as defined in IC 27-13-1-19).

(5) A pharmacy benefit manager (as defined in IC 27-1-24.8-3).

(6) A third party administrator.

(7) An insurer (as defined in IC 27-1-26-1), excluding insurers of life insurance.

(8) Any other person identified by the commissioner for participation in the data base described in this chapter.

Sec. 3. (a) Before July 1, 2020, the department shall issue a request for information in compliance with IC 5-23-4.5 concerning the creation, operation, and maintenance of a data base.

(b) The request for information must include the following questions:

(1) How the person would collect all relevant claims data for the data base from a health payer in a manner that would minimize technical barriers for a health payer to submit a claim.

(2) How the person would promote and encourage self funded plans to voluntarily submit claims data for inclusion in the data base.

(3) What funding sources the person would seek to offset costs to implement and maintain the data base.

(4) How the person would make data from the data base available, including what sufficient fee would need to be assessed, to researchers, companies, and other interested parties in analyzing the data.

(5) How the person would ensure the following:

(A) That data is submitted and released in a machine-readable format.

(B) That the data from the data base is used in an ethical manner.

(C) That the data is not personally identifiable and is properly secured and maintained, and that the person complies with federal and state health care privacy laws.

(6) How the person would establish a public web portal for individuals to quickly and easily compare prices for the full spectrum of medical billing codes as well as check quality ratings of providers.

(7) What threshold should be set for health payers to submit data for the data base.

(8) How the person would work with other states and relevant stakeholders to either:

(A) use a data language that is already available; or

(B) facilitate the establishment of a common data language to be used by states for the data.

(9) Whether any changes to state law would increase the functionality and effectiveness of the data base and recommendations of the statutes and necessary changes.

(10) Whatever other questions the department determines is relevant to the implementation of a robust and transparent

data base.

(c) The department shall set the deadline for submissions of the request for information under this section that may be not later than November 30, 2020.

Sec. 4. (a) After May 30, 2021, but before June 15, 2021, the department shall issue a request for proposals for a person to create, operate, and maintain the data base under this chapter. In addition to the requirements of IC 5-22-9, the request for proposals must include the considerations contained in the request for information under section 3 of this chapter.

(b) The request for proposals must state that the data base's purpose is to facilitate the following:

(1) Identifying health care needs and informing health care policy.

(2) Comparing costs between various treatment settings and approaches.

(3) Providing information to consumers and purchasers of health care.

(4) Improving the quality and affordability of patient health care and health care coverage.

(c) Submissions for the request for proposals under this section must occur not later than September 30, 2021.

(d) The department shall publish the department's decision concerning the submissions not later than November 30, 2021.

(e) If the department accepts a submission for the request for proposals, the department shall enter into a contract with the person to act as administrator of the data base and develop the data base not later than June 30, 2022.

(f) The administrator shall ensure that the data base is secure and compliant with the federal Health Insurance Portability and Accountability Act (HIPAA).

Sec. 5. A health payer shall begin submitting the required data in a format specified by the administrator of the data base not later than three (3) months from the first day the department declares the data base to be fully operational.

SECTION 36. IC 27-2-25 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 25. Health Carrier Good Faith Estimates

Sec. 1. As used in this chapter, "coverage" means the right of an individual to receive:

(1) health care services; or

(2) payment or reimbursement for health care services;

from a health carrier.

Sec. 2. As used in this chapter, "covered individual" means an individual who is entitled to coverage from a health carrier.

Sec. 3. As used in this chapter, "good faith estimate" means a health carrier's reasonable estimate of:

(1) the amount of the cost of a nonemergency health care service that the health carrier will:

(A) pay for; or

(B) reimburse to;

a covered individual; or

(2) the extent and nature of the nonemergency health care service a covered individual is entitled to receive;

that a health carrier provides upon request to a covered individual for whom a nonemergency health care service has been ordered.

Sec. 4. (a) As used in this chapter, "health carrier" means an entity:

(1) that is subject to this title and the administrative rules adopted under this title; and

(2) that enters into a contract to:

(A) provide health care services;

(B) deliver health care services;

(C) arrange for health care services; or

(D) pay for or reimburse any of the costs of health care services.

(b) The term includes the following:

(1) An insurer, as defined in IC 27-1-2-3(x), that issues a policy of accident and sickness insurance, as defined in IC 27-8-5-1(a).

(2) A health maintenance organization, as defined in IC 27-13-1-19.

(3) An administrator (as defined in IC 27-1-25-1(a)) that is licensed under IC 27-1-25.

(4) Any other entity that provides a plan of health insurance, health benefits, or health care services.

Sec. 5. As used in this chapter, "in network", when used in reference to a practitioner, means that the health care services provided by the practitioner are subject to a health carrier's network plan.

Sec. 6. (a) As used in this chapter, "network" means a group of provider facilities and practitioners that:

(1) provide health care services to covered individuals; and

(2) have agreed to, or are otherwise subject to, maximum limits on the fees and charges for the health care services to be provided to the covered individuals.

(b) The term includes the following:

(1) A network described in subsection (a) that is established pursuant to a contract between an insurer providing coverage under a group health policy and:

(A) individual provider facilities and practitioners;

(B) a preferred provider organization; or

(C) an entity that employs or represents providers, including:

(i) an independent practice association; and

(ii) a physician-hospital organization.

(2) A health management organization, as defined in IC 27-13-1-19.

Sec. 7. As used in this chapter, "network plan" means a plan of a health carrier that:

(1) requires a covered person to receive; or

(2) creates incentives, including financial incentives, for a covered person to receive;

health care services from one (1) or more providers that are under contract with, managed by, or owned by the health carrier.

Sec. 8. (a) As used in this chapter, "nonemergency health care service" means a service or series of services ordered, scheduled, or referred by a practitioner for the:

(1) diagnosis;

(2) prevention;

(3) treatment;

(4) cure; or

(5) relief;

of a physical, mental, or behavioral health condition, illness, injury, or disease that is not provided on an emergency basis.

Sec. 9. As used in this chapter, "practitioner" means:

(1) an individual who holds a license, certificate, registration, or permit under:

(A) IC 25-22.5 (physicians);

(B) IC 25-27 (physical therapists); or

(C) IC 25-33 (psychologists); or

(2) an organization consisting of or employing two (2) or more individuals described in subdivision (1).

Sec. 9.5. As used in this chapter, "price" means the negotiated rate between the:

(1) provider facility and practitioner; and

(2) covered individual's health carrier;

minus the amount that the health carrier will pay.

Sec. 10. As used in this chapter, "provider" means:

(1) a provider facility; or

(2) a practitioner.

Sec. 11. As used in this chapter, "provider facility"means any of the following:

(1) A hospital licensed under IC 16-21-2.

(2) An ambulatory outpatient surgery center licensed under IC 16-21-2.

(3) An abortion clinic licensed under IC 16-21-2.

(4) A birthing center licensed under IC 16-21-2.

(5) A facility that provides diagnostic services to the medical profession or the general public.

(6) A laboratory where clinical pathology tests are carried out on specimens to obtain information about the health of a patient.

(7) A facility where radiologic and electromagnetic images are made to obtain information about the health of a patient.

(8) An infusion center that administers intravenous medications.

Sec. 12. (a) A covered individual for whom a nonemergency health care service has been ordered may request from the health carrier a good faith estimate of:

(1) the amount of the cost of the nonemergency health care service that the health carrier will:

(A) pay for; or

(B) reimburse to;

the covered individual; or

(2) the extent and nature of the ordered nonemergency health care service a covered individual is entitled to receive from the health carrier.

(b) If:

(1) a health carrier provides coverage to a covered individual through a network plan; and

(2) the health carrier receives a request for a good faith estimate from a covered individual for whom a nonemergency health care service has been ordered;

the health carrier shall inform the covered individual whether the provider facility in which the nonemergency health care service will be provided is in network and whether each scheduled

practitioner who will provide the nonemergency health care service is in network.

(c) A health carrier that receives a request from a covered individual patient under subsection (b) shall, not more than three (3) business days after receiving the request, provide to the individual a good faith estimate as described in section 14 of this chapter.

(d) A health carrier must ensure that a good faith estimate provided to an individual under this section is accompanied by a notice stating that:

(1) the amount that the health carrier will:

(A) pay; or

(B) reimburse;

for or to the covered individual for the nonemergency health care services the individual receives; and

(2) the nature and extent of the nonemergency health care services the individual will receive;

may vary from the health carrier's good faith estimate based on the individual's medical needs.

(e) A health carrier may not charge an individual for information provided under this section.

(f) A practitioner and provider facility must provide a health carrier with timely information needed by the health carrier to comply with the requirements under this chapter.

Sec. 13. A health carrier may provide a good faith estimate to an individual under this chapter:

(1) in a writing delivered to the individual; or

(2) by electronic mail;

according to the preference expressed by the individual.

Sec. 14. (a) A good faith estimate provided by a health carrier to an individual under this chapter must:

(1) in the case of an insurer or another health carrier that pays or reimburses the cost of health care services:

(A) state the services and material items that the good faith estimate is based on;

(B) set forth for the services and material items referred to in clause (A) the amount that the health carrier will:

(i) pay; or

(ii) reimburse;

for or to the covered individual for the service or material item;

(C) include a total figure that is a sum of the amounts

referred to in clause (B); and

(D) state the out-of-pocket costs the covered individual will incur, if any, beyond the amount that the health carrier will pay or reimburse; and

(2) in the case of a health maintenance organization or another health carrier that provides health care services:

(A) state the nature and extent of the health care services to which the covered individual is entitled; and

(B) state the out-of-pocket costs the covered individual will incur, if any, beyond being provided the health care services referred to in clause (A).

(b) A practitioner and provider facility must provide a health carrier with timely information needed by the health carrier comply to with the requirements under this chapter.

Sec. 15. A health carrier that provides an Internet web site for the use of its covered individuals shall ensure that the Internet web site includes a printed notice that:

(1) is designed, lettered, and featured on the Internet web site so as to be conspicuous to and readable by any individual with normal vision who visits the Internet web site; and

(2) states the following, or words to the same effect: "A covered individual may at any time ask the health carrier for an estimate of the amount the health carrier will pay for or reimburse to a covered individual for nonemergency health care services that have been ordered for the covered individual or the nature and extent of the ordered nonemergency health care services a covered individual is entitled to receive from the health carrier. The law requires that an estimate be provided within 3 business days.".

Sec. 16. (a) If a health carrier fails or refuses:

(1) to provide a good faith estimate as required by this chapter; or

(2) to provide notice on the health carrier's Internet web site as required by section 15 of this chapter;

the insurance commissioner may, after notice and hearing under IC 4-21.5, impose on the health carrier a civil penalty of not more than one thousand dollars ($1,000) for each day of noncompliance.

(b) A civil penalty collected under this section shall be deposited in the department of insurance fund established by IC 27-1-3-28.

SECTION 37. IC 27-4-1-4, AS AMENDED BY P.L.124-2018, SECTION 64, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 4. (a) The following are hereby defined as unfair

methods of competition and unfair and deceptive acts and practices in the business of insurance:

(1) Making, issuing, circulating, or causing to be made, issued, or circulated, any estimate, illustration, circular, or statement:

(A) misrepresenting the terms of any policy issued or to be issued or the benefits or advantages promised thereby or the dividends or share of the surplus to be received thereon;

(B) making any false or misleading statement as to the dividends or share of surplus previously paid on similar policies;

(C) making any misleading representation or any misrepresentation as to the financial condition of any insurer, or as to the legal reserve system upon which any life insurer operates;

(D) using any name or title of any policy or class of policies misrepresenting the true nature thereof; or

(E) making any misrepresentation to any policyholder insured in any company for the purpose of inducing or tending to induce such policyholder to lapse, forfeit, or surrender the policyholder's insurance.

(2) Making, publishing, disseminating, circulating, or placing before the public, or causing, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, in a newspaper, magazine, or other publication, or in the form of a notice, circular, pamphlet, letter, or poster, or over any radio or television station, or in any other way, an advertisement, announcement, or statement containing any assertion, representation, or statement with respect to any person in the conduct of the person's insurance business, which is untrue, deceptive, or misleading.

(3) Making, publishing, disseminating, or circulating, directly or indirectly, or aiding, abetting, or encouraging the making, publishing, disseminating, or circulating of any oral or written statement or any pamphlet, circular, article, or literature which is false, or maliciously critical of or derogatory to the financial condition of an insurer, and which is calculated to injure any person engaged in the business of insurance.

(4) Entering into any agreement to commit, or individually or by a concerted action committing any act of boycott, coercion, or intimidation resulting or tending to result in unreasonable restraint of, or a monopoly in, the business of insurance.

(5) Filing with any supervisory or other public official, or making,

publishing, disseminating, circulating, or delivering to any person, or placing before the public, or causing directly or indirectly, to be made, published, disseminated, circulated, delivered to any person, or placed before the public, any false statement of financial condition of an insurer with intent to deceive. Making any false entry in any book, report, or statement of any insurer with intent to deceive any agent or examiner lawfully appointed to examine into its condition or into any of its affairs, or any public official to which such insurer is required by law to report, or which has authority by law to examine into its condition or into any of its affairs, or, with like intent, willfully omitting to make a true entry of any material fact pertaining to the business of such insurer in any book, report, or statement of such insurer.

(6) Issuing or delivering or permitting agents, officers, or employees to issue or deliver, agency company stock or other capital stock, or benefit certificates or shares in any common law corporation, or securities or any special or advisory board contracts or other contracts of any kind promising returns and profits as an inducement to insurance.

(7) Making or permitting any of the following:

(A) Unfair discrimination between individuals of the same class and equal expectation of life in the rates or assessments charged for any contract of life insurance or of life annuity or in the dividends or other benefits payable thereon, or in any other of the terms and conditions of such contract. However, in determining the class, consideration may be given to the nature of the risk, plan of insurance, the actual or expected expense of conducting the business, or any other relevant factor.

(B) Unfair discrimination between individuals of the same class involving essentially the same hazards in the amount of premium, policy fees, assessments, or rates charged or made for any policy or contract of accident or health insurance or in the benefits payable thereunder, or in any of the terms or conditions of such contract, or in any other manner whatever. However, in determining the class, consideration may be given to the nature of the risk, the plan of insurance, the actual or expected expense of conducting the business, or any other relevant factor.

(C) Excessive or inadequate charges for premiums, policy fees, assessments, or rates, or making or permitting any unfair discrimination between persons of the same class involving

essentially the same hazards, in the amount of premiums, policy fees, assessments, or rates charged or made for:

(i) policies or contracts of reinsurance or joint reinsurance, or abstract and title insurance;

(ii) policies or contracts of insurance against loss or damage to aircraft, or against liability arising out of the ownership, maintenance, or use of any aircraft, or of vessels or craft, their cargoes, marine builders' risks, marine protection and indemnity, or other risks commonly insured under marine, as distinguished from inland marine, insurance; or

(iii) policies or contracts of any other kind or kinds of insurance whatsoever.

However, nothing contained in clause (C) shall be construed to apply to any of the kinds of insurance referred to in clauses (A) and (B) nor to reinsurance in relation to such kinds of insurance. Nothing in clause (A), (B), or (C) shall be construed as making or permitting any excessive, inadequate, or unfairly discriminatory charge or rate or any charge or rate determined by the department or commissioner to meet the requirements of any other insurance rate regulatory law of this state.

(8) Except as otherwise expressly provided by law, knowingly permitting or offering to make or making any contract or policy of insurance of any kind or kinds whatsoever, including but not in limitation, life annuities, or agreement as to such contract or policy other than as plainly expressed in such contract or policy issued thereon, or paying or allowing, or giving or offering to pay, allow, or give, directly or indirectly, as inducement to such insurance, or annuity, any rebate of premiums payable on the contract, or any special favor or advantage in the dividends, savings, or other benefits thereon, or any valuable consideration or inducement whatever not specified in the contract or policy; or giving, or selling, or purchasing or offering to give, sell, or purchase as inducement to such insurance or annuity or in connection therewith, any stocks, bonds, or other securities of any insurance company or other corporation, association, limited liability company, or partnership, or any dividends, savings, or profits accrued thereon, or anything of value whatsoever not specified in the contract. Nothing in this subdivision and subdivision (7) shall be construed as including within the definition of discrimination or rebates any of the following practices:

(A) Paying bonuses to policyholders or otherwise abating their

premiums in whole or in part out of surplus accumulated from nonparticipating insurance, so long as any such bonuses or abatement of premiums are fair and equitable to policyholders and for the best interests of the company and its policyholders.

(B) In the case of life insurance policies issued on the industrial debit plan, making allowance to policyholders who have continuously for a specified period made premium payments directly to an office of the insurer in an amount which fairly represents the saving in collection expense.

(C) Readjustment of the rate of premium for a group insurance policy based on the loss or expense experience thereunder, at the end of the first year or of any subsequent year of insurance thereunder, which may be made retroactive only for such policy year.

(D) Paying by an insurer or insurance producer thereof duly licensed as such under the laws of this state of money, commission, or brokerage, or giving or allowing by an insurer or such licensed insurance producer thereof anything of value, for or on account of the solicitation or negotiation of policies or other contracts of any kind or kinds, to a broker, an insurance producer, or a solicitor duly licensed under the laws of this state, but such broker, insurance producer, or solicitor receiving such consideration shall not pay, give, or allow credit for such consideration as received in whole or in part, directly or indirectly, to the insured by way of rebate.

(9) Requiring, as a condition precedent to loaning money upon the security of a mortgage upon real property, that the owner of the property to whom the money is to be loaned negotiate any policy of insurance covering such real property through a particular insurance producer or broker or brokers. However, this subdivision shall not prevent the exercise by any lender of the lender's right to approve or disapprove of the insurance company selected by the borrower to underwrite the insurance.

(10) Entering into any contract, combination in the form of a trust or otherwise, or conspiracy in restraint of commerce in the business of insurance.

(11) Monopolizing or attempting to monopolize or combining or conspiring with any other person or persons to monopolize any part of commerce in the business of insurance. However, participation as a member, director, or officer in the activities of any nonprofit organization of insurance producers or other workers in the insurance business shall not be interpreted, in

itself, to constitute a combination in restraint of trade or as combining to create a monopoly as provided in this subdivision and subdivision (10). The enumeration in this chapter of specific unfair methods of competition and unfair or deceptive acts and practices in the business of insurance is not exclusive or restrictive or intended to limit the powers of the commissioner or department or of any court of review under section 8 of this chapter.

(12) Requiring as a condition precedent to the sale of real or personal property under any contract of sale, conditional sales contract, or other similar instrument or upon the security of a chattel mortgage, that the buyer of such property negotiate any policy of insurance covering such property through a particular insurance company, insurance producer, or broker or brokers. However, this subdivision shall not prevent the exercise by any seller of such property or the one making a loan thereon of the right to approve or disapprove of the insurance company selected by the buyer to underwrite the insurance.

(13) Issuing, offering, or participating in a plan to issue or offer, any policy or certificate of insurance of any kind or character as an inducement to the purchase of any property, real, personal, or mixed, or services of any kind, where a charge to the insured is not made for and on account of such policy or certificate of insurance. However, this subdivision shall not apply to any of the following:

(A) Insurance issued to credit unions or members of credit unions in connection with the purchase of shares in such credit unions.

(B) Insurance employed as a means of guaranteeing the performance of goods and designed to benefit the purchasers or users of such goods.

(C) Title insurance.

(D) Insurance written in connection with an indebtedness and intended as a means of repaying such indebtedness in the event of the death or disability of the insured.

(E) Insurance provided by or through motorists service clubs or associations.

(F) Insurance that is provided to the purchaser or holder of an air transportation ticket and that:

(i) insures against death or nonfatal injury that occurs during the flight to which the ticket relates;

(ii) insures against personal injury or property damage that

occurs during travel to or from the airport in a common carrier immediately before or after the flight;

(iii) insures against baggage loss during the flight to which the ticket relates; or

(iv) insures against a flight cancellation to which the ticket relates.

(14) Refusing, because of the for-profit status of a hospital or medical facility, to make payments otherwise required to be made under a contract or policy of insurance for charges incurred by an insured in such a for-profit hospital or other for-profit medical facility licensed by the state department of health.

(15) Refusing to insure an individual, refusing to continue to issue insurance to an individual, limiting the amount, extent, or kind of coverage available to an individual, or charging an individual a different rate for the same coverage, solely because of that individual's blindness or partial blindness, except where the refusal, limitation, or rate differential is based on sound actuarial principles or is related to actual or reasonably anticipated experience.

(16) Committing or performing, with such frequency as to indicate a general practice, unfair claim settlement practices (as defined in section 4.5 of this chapter).

(17) Between policy renewal dates, unilaterally canceling an individual's coverage under an individual or group health insurance policy solely because of the individual's medical or physical condition.

(18) Using a policy form or rider that would permit a cancellation of coverage as described in subdivision (17).

(19) Violating IC 27-1-22-25, IC 27-1-22-26, or IC 27-1-22-26.1 concerning motor vehicle insurance rates.

(20) Violating IC 27-8-21-2 concerning advertisements referring to interest rate guarantees.

(21) Violating IC 27-8-24.3 concerning insurance and health plan coverage for victims of abuse.

(22) Violating IC 27-8-26 concerning genetic screening or testing.

(23) Violating IC 27-1-15.6-3(b) concerning licensure of insurance producers.

(24) Violating IC 27-1-38 concerning depository institutions.

(25) Violating IC 27-8-28-17(c) or IC 27-13-10-8(c) concerning the resolution of an appealed grievance decision.

(26) Violating IC 27-8-5-2.5(e) through IC 27-8-5-2.5(j) (expired July 1, 2007, and removed) or IC 27-8-5-19.2 (expired July 1,

2007, and repealed).

(27) Violating IC 27-2-21 concerning use of credit information.

(28) Violating IC 27-4-9-3 concerning recommendations to consumers.

(29) Engaging in dishonest or predatory insurance practices in marketing or sales of insurance to members of the United States Armed Forces as:

(A) described in the federal Military Personnel Financial Services Protection Act, P.L.109-290; or

(B) defined in rules adopted under subsection (b).

(30) Violating IC 27-8-19.8-20.1 concerning stranger originated life insurance.

(31) Violating IC 27-2-22 concerning retained asset accounts.

(32) Violating IC 27-8-5-29 concerning health plans offered through a health benefit exchange (as defined in IC 27-19-2-8).

(33) Violating a requirement of the federal Patient Protection and Affordable Care Act (P.L. 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (P.L. 111-152), that is enforceable by the state.

(34) After June 30, 2015, violating IC 27-2-23 concerning unclaimed life insurance, annuity, or retained asset account benefits.

(35) Willfully violating IC 27-1-12-46 concerning a life insurance policy or certificate described in IC 27-1-12-46(a).

(36) Violating IC 27-1-37-7 concerning prohibiting the disclosure of health care services claims data.

(b) Except with respect to federal insurance programs under Subchapter III of Chapter 19 of Title 38 of the United States Code, the commissioner may, consistent with the federal Military Personnel Financial Services Protection Act (10 U.S.C. 992 note), adopt rules under IC 4-22-2 to:

(1) define; and

(2) while the members are on a United States military installation or elsewhere in Indiana, protect members of the United States Armed Forces from;

dishonest or predatory insurance practices.

SECTION 38. IC 27-8-11-13 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2021]: **Sec. 13. (a) A fully credentialed provider shall be reimbursed for eligible services provided at any in-network hospital if the following conditions are met:**

(1) The provider submits the documentation required by the

insurer to be loaded under the provider group or hospital.

(2) The provider, provider group, or hospital is a network provider with the insurer.

(3) The services are provided in accordance with all terms and conditions of the provider's, group provider's, or hospital's agreement or contract with the insurer.

(4) Prior authorization is obtained in accordance with IC 27-1-37.5 when required by the insurer for an eligible service.

(b) The insurer shall reimburse the provider or hospital for services described in subsection (a) at the rates determined by the contract between the provider and the insurer.

(c) An insurer is not required to credential a provider. However, if:

(1) a provider is employed by a hospital that is part of the hospital's network that is covered by the insurer; and

(2) the provider meets the insurer's credentialing requirements;

the insurer shall reimburse the provider for any reimbursable services from the date that the provider was employed by the hospital.

SECTION 39. IC 27-13-43-4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2021]: **Sec. 4. (a) A fully credentialed provider shall be reimbursed for eligible services provided at any in-network hospital if the following conditions are met:**

(1) The provider submits the documentation required by the health maintenance organization to be loaded under the provider group or hospital.

(2) The provider, provider group, or hospital is a network provider with the health maintenance organization.

(3) The services are provided in accordance with all terms and conditions of the provider's, group provider's, or hospital's agreement or contract with the health maintenance organization.

(4) Prior authorization is obtained in accordance with IC 27-1-37.5 when required by the health maintenance organization for an eligible service.

(b) The health maintenance organization shall reimburse the provider or hospital for services described in subsection (a) at the rates determined by the contract between the provider and the health maintenance organization.

(c) A health maintenance organization is not required to credential a provider. However, if:

(1) a provider is employed by a hospital that is part of the hospital's network that is covered by the health maintenance organization; and

(2) the provider meets the health maintenance organization's credentialing requirements;

the health maintenance organization shall reimburse the provider for any reimbursable services from the date that the provider was employed by the hospital.

SECTION 40. IC 36-2-14-21, AS AMENDED BY P.L.1-2007, SECTION 240, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 21. (a) As used in this section, "health records" means written, electronic, or printed information possessed by a provider concerning any diagnosis, treatment, or prognosis of the patient. The term includes mental health records, alcohol and drug abuse records, and emergency ambulance service records.

(b) As used in this section, "provider" has the meaning set forth in ~~IC 16-18-2-295(b).~~ **IC 16-18-2-295(c).**

(c) As part of a medical examination or autopsy conducted under this chapter, a coroner may obtain a copy of the decedent's health records.

(d) Except as provided in subsection (e), health records obtained under this section are confidential.

(e) The coroner may provide the health records of a decedent that were obtained under this section to a prosecuting attorney or law enforcement agency that is investigating the individual's death. Health records received from a coroner under this subsection are confidential.

(f) A person who receives confidential records or information under this section and knowingly or intentionally discloses the records or information to an unauthorized person commits a Class A misdemeanor.

SECTION 41. **An emergency is declared for this act.**

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1005, 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 6, delete lines 19 through 23, begin a new paragraph and insert:

"SECTION 5. IC 16-18-2-163.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 163.6. "Health care services", for purposes of IC 16-51-1, has the meaning set forth in IC 16-51-1-1.**".

Page 6, line 26, after "163.8." insert "**(a)**".

Page 6, between lines 28 and 29, begin a new paragraph and insert:

"**(b) "Health carrier", for purposes of IC 16-51-2, has the meaning set forth in IC 16-51-2-1.**".

Page 7, delete lines 3 through 7.

Page 7, between lines 38 and 39, begin a new paragraph and insert:

"**(f) "Practitioner", for purposes of IC 16-51-1, has the meaning set forth in IC 16-51-1-4.**".

Page 8, between lines 40 and 41, begin a new paragraph and insert:

"**(f) "Provider", for purposes of IC 16-51-2, has the meaning set forth in IC 16-51-2-2.**".

Page 9, delete lines 4 through 40, begin a new paragraph and insert:

"SECTION 17. IC 16-18-2-328.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 328.7. "Service facility location", for purposes of IC 16-51-1, has the meaning set forth in IC 16-51-1-6.**

SECTION 18. IC 16-18-2-362.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 362.1. "Urgent care facility", for purposes of IC 16-24.5-1, has the meaning set forth in IC 16-24.5-1-1.**".

Page 10, line 19, after "estimate" insert "**within three (3) business days**".

Page 10, line 20, delete "or" and insert "**.**".

Page 10, delete lines 21 through 24.

Page 10, between lines 28 and 29, begin a new paragraph and insert:

"**Sec. 0.5. Nothing in this chapter prohibits:**

(1) a self-funded health benefit plan that complies with the federal Employee Retirement Income Security Act (ERISA)

of 1974 (29 U.S.C. 1001 et seq.); or

(2) a self-insurance program established to provide group health coverage as described in IC 5-10-8-7(b), or a contract for health services as described in IC 5-10-8-7(c);

from providing information requested by a practitioner or provider facility under this chapter.".

Page 10, line 33, delete "realistic, honest" and insert "**reasonable**".

Page 10, line 33, delete "amount" and insert "**price**".

Page 12, line 6, after "services" insert "**ordered, scheduled, or referred by a practitioner**".

Page 12, line 6, delete "the:" and insert "**the purpose of:**".

Page 12, line 18, after "therapists);" insert "**or**".

Page 12, delete line 19.

Page 12, line 20, delete "(D)" and insert "**(C)**".

Page 12, delete line 21.

Page 12, between lines 23 and 24, begin a new paragraph and insert:

"**Sec. 8.5. As used in this chapter, "price" means the negotiated rate between the:**

(1) provider facility and practitioner; and

(2) covered individual's health carrier.".

Page 12, line 35, delete "." and insert "**, including outpatient facilities.**".

Page 12, between lines 40 and 41, begin a new line block indented and insert:

"**(8) An infusion center that administers intravenous medications.**".

Page 12, line 41, after "not" insert "**:**

(1)".

Page 12, line 42, delete "recipient." and insert "**recipient; or**

(2) limit the authority of a legal representative of the patient.".

Page 13, line 4, delete "amount" and insert "**price**".

Page 13, line 7, delete "seventy-two (72) hours" and insert "**three (3) business days**".

Page 13, line 10, delete "charge" and insert "**price**".

Page 13, line 22, delete "and" and insert "**,**".

Page 13, line 23, delete ":" and insert "**, and other persons who provide professional health services:**".

Page 13, line 39, delete "amount" and insert "**price**".

Page 14, line 4, delete "is" and insert "**and has been verified as**".

Page 14, line 27, delete "or".

Page 14, line 28, after "mail;" insert "**or**

(3) through a mobile application;".

Page 14, line 34, delete "charge" and insert "**price**".

Page 14, line 36, delete "charges" and insert "**prices**".

Page 14, after line 42, begin a new paragraph and insert:

"**(c) A health carrier must provide a provider facility with timely information needed by the provider facility to comply with the requirements under this chapter.**".

Page 15, line 2, delete "wait" and insert "**check in or register**".

Page 15, line 14, after "for a" insert "**nonemergency**".

Page 15, line 14, delete "In".

Page 15, line 15, delete "nonemergency situations, the" and insert "**The**".

Page 15, line 16, delete "72 hours." and insert "**3 business days.**".

Page 15, line 24, delete "at any time".

Page 15, line 25, after "for a" insert "**nonemergency**".

Page 15, line 26, delete "In nonemergency situations, the" and insert "**The**".

Page 15, line 27, delete "72 hours." and insert "**3 business days.**".

Page 15, delete lines 28 through 42.

Page 16, delete lines 1 through 25.

Page 16, line 33, delete "chapter." and insert "**chapter for the following:**

(1) For as many of the seventy (70) shoppable services specified in 45 CFR 180 (as published August 9, 2019, and as subsequently amended) that are provided by the hospital or ambulatory outpatient surgical center.

(2) In addition to the services specified in subdivision (1), the thirty (30) most common services that are provided by the hospital or ambulatory outpatient surgical center.".

Page 17, delete lines 3 through 5.

Page 17, line 6, delete "(E)" and insert "**(C)**".

Page 17, line 8, delete "(F)" and insert "**(D)**".

Page 17, line 8, delete "." and insert "**without charitable assistance from the hospital or ambulatory surgical center.**

(E) Self pay with charitable assistance from the hospital or ambulatory surgical center.".

Page 17, between lines 14 and 15, begin a new paragraph and insert:

"SECTION 22. IC 16-24.5 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

ARTICLE 24.5. OTHER HEALTH CARE FACILITIES

Chapter 1. Urgent Care Facilities

Sec. 1. (a) As used in this chapter, "urgent care facility" means

a free standing health care facility that offers episodic, walk-in care for the treatment of acute, but not life-threatening, health conditions.

(b) The term does not include an emergency department of a hospital or a nonprofit or government operated health clinic.

Sec. 2. (a) Not later than March 31, 2021, an urgent care facility shall post on the Internet web site of the urgent care facility pricing and other information specified in this chapter for the fifteen (15) most common services that are provided by the urgent care facility.

(b) The following information must be included on the Internet web site by an urgent care facility for each billing code, including, if relevant, each diagnosis related group (DRG) billing code and each health care common procedure coding system (HCPCS) billing code:

(1) The number of services provided for the code.

(2) A description of the service.

(3) The weighted average prices paid per service per provider type for each of the following categories:

(A) Employer sponsored insurance.

(B) Individually purchased insurance.

(C) Medicare, including fee for service and Medicare Advantage.

(D) Self pay without charitable assistance from the hospital or ambulatory surgical center.

(E) Self pay with charitable assistance from the hospital or ambulatory surgical center.

Sec. 3. (a) The information displayed on the Internet web site must be in an easy to read, understandable format, and include the prices for each billing code by provider type.

(b) An urgent care facility shall update the information on the Internet web site on a quarterly basis.

SECTION 23. IC 16-51 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

ARTICLE 51. HEALTH CARE REQUIREMENTS

Chapter 1. Health Care Billing

Sec. 1. (a) As used in this chapter, "health care services" means health care related services or products rendered or sold by a provider within the scope of the provider's license or legal authorization.

(b) The term includes hospital, medical, surgical, dental, vision,

and pharmaceutical services or products.

Sec. 2. As used in this chapter, "health maintenance organization" has the meaning set forth in IC 27-13-1-19.

Sec. 3. As used in this chapter, "insurer" has the meaning set forth in IC 27-8-11-1(e).

Sec. 4. As used in this chapter, "practitioner" means an individual or entity duly licensed or legally authorized to provide health care services.

Sec. 5. As used in this chapter, "provider facility" means any of the following:

(1) A hospital.

(2) A skilled nursing facility.

(3) An end stage renal disease provider.

(4) A home health agency.

(5) A hospice organization.

(6) An outpatient physical therapy, occupational therapy, or speech pathology service provider.

(7) A comprehensive outpatient rehabilitation facility.

(8) A community mental health center.

(9) A critical access hospital.

(10) A federally qualified health center.

(11) A histocompatibility laboratory.

(12) An Indian health service facility.

(13) An organ procurement organization.

(14) A religious nonmedical health care institution.

(15) A rural health clinic.

Sec. 6. As used in this chapter, "service facility location" means the address where the services of a provider facility or practitioner were provided. The term consists of exact address and place of service codes as required on CMS forms 1500 and 1450, including an office, on-campus location of a hospital, and off-campus location of a hospital.

Sec. 7. (a) A provider facility or practitioner shall include the address of the service facility location in order to obtain reimbursement for a commercial claim for health care services from an insurer, health maintenance organization, employer, or other person responsible for the payment of the cost of health care services.

(b) An insurer, health maintenance organization, employer, or other person responsible for the payment of the cost of health care services is not required to accept a bill for health care services that does not contain the service facility location.

Sec. 8. A patient is not liable for any additional payment that is the result of a practitioner or provider facility filing an incorrect form or not including the correct service facility location as required under this chapter.

Chapter 2. Centralized Credentialing

Sec. 1. (a) As used in this chapter, "health carrier" means an entity:

(1) that is subject to IC 27 and the administrative rules adopted under IC 27; and

(2) that enters into a contract to:

(A) provide health care services;

(B) deliver health care services;

(C) arrange for health care services; or

(D) pay for or reimburse any of the costs of health care services.

(b) The term includes the following:

(1) An insurer, as defined in IC 27-1-2-3(x), that issues a policy of accident and sickness insurance, as defined in IC 27-8-5-1(a).

(2) A health maintenance organization, as defined in IC 27-13-1-19.

(3) An administrator (as defined in IC 27-1-25-1(a)) that is licensed under IC 27-1-25.

(4) Any other entity that provides a plan of health insurance, health benefits, or health care services.

Sec. 2. As used in this chapter, "provider" has the meaning set forth in IC 16-18-2-295(c)(1).

Sec. 3. (a) The department shall implement a centralized credentials verification organization and credentialing process that:

(1) uses a common application, as determined by provider type;

(2) issues a single credentialing decision applicable to all health carriers, except as determined by the department;

(3) recredentials and revalidates provider information not less than once every three (3) years;

(4) requires attestation of enrollment and credentialing information every six (6) months; and

(5) is certificated or accredited by the National Committee for Quality Assurance or its successor organization.

(b) A health carrier may not require additional credentialing requirements in order to participate in a health carrier's network.

However, a health carrier may collect additional information from the provider in order to complete a contract or provider agreement.

(c) A health carrier is not required to contract with a provider. However, if a provider is employed by a health care facility that is covered by the health carrier or in the health carrier's network and the provider meets the credentialing requirements under this chapter, the health carrier shall reimburse the provider for any reimbursable services from the date that the provider was employed by the health care facility.

(d) A credentialed provider may be employed by multiple health care facilities.

(e) Except when a provider's professional license is no longer valid, a credential acquired under this chapter is valid until recredentialing is required.

(f) An adverse action under this section is subject to IC 4-21.5.

(g) The department may adopt rules under IC 4-22-2 to implement this section.

(h) The department may adopt emergency rules to implement this section. However, an emergency rule adopted under this section expires the earlier of:

(1) one (1) year after the rule was accepted for filing under IC 4-22-2-37.1(e); or

(2) June 30, 2021.

This subsection expires July 1, 2021.".

Page 17, line 23, delete "realistic, honest" and insert "**reasonable**".

Page 17, line 23, delete "amount" and insert "**price**".

Page 18, line 41, after "services" insert "**ordered, scheduled, or referred by a practitioner**".

Page 19, line 11, after "therapists);" insert "**or**".

Page 19, delete line 12.

Page 19, line 13, delete "(D)" and insert "**(C)**".

Page 19, delete line 14.

Page 19, between lines 16 and 17, begin a new paragraph and insert:

"**Sec. 8.5. As used in this chapter, "price" means the negotiated rate between the:**

(1) provider facility and practitioner; and

(2) covered individual's health carrier.".

Page 19, between lines 33 and 34, begin a new line block indented and insert:

"**(8) An infusion center that administers intravenous medications.**".

Page 19, line 39, delete "amount" and insert "**price**".

Page 19, line 42, delete "seventy-two (72) hours" and insert "**three (3) business days**".

Page 20, line 2, after "total" insert "**price**".

Page 20, line 37, delete "or".

Page 20, line 38, after "mail;" insert "**or**

(3) through a mobile application;".

Page 21, line 2, delete "charge" and insert "**price**".

Page 21, line 4, delete "charges" and insert "**prices**".

Page 21, between lines 10 and 11, begin a new paragraph and insert:

"**(c) A health carrier must provide a practitioner with timely information needed by the practitioner to comply with the requirements under this chapter.**".

Page 21, delete lines 21 through 42, begin a new paragraph and insert:

"**Sec. 16. (a) A practitioner that has ordered, scheduled, or referred the individual for a nonemergency health care service shall provide to the individual an electronic or paper copy of a written notice that states the following, or words to the same effect: "A patient may at any time ask a practitioner for an estimate of the amount the practitioner will charge for providing a nonemergency medical service. The law requires that the estimate be provided within 3 business days.".**

(b) The state department may adopt rules under IC 4-22-2 to establish requirements for practitioners to provide additional charging information under this section.".

Page 22, delete lines 1 through 2.

Page 22, line 18, after "13.5." insert "**(a)**".

Page 22, between lines 28 and 29, begin a new paragraph and insert:

"**(b) A copy of the written notification required under this section must be signed by the client.**".

Page 22, line 31, after "to" insert "**:**

(1)".

Page 22, line 31, after "contracts" insert "**; and**

(2) contracts between a provider and a pharmacy benefits manager;".

Page 22, line 32, after "renewed" insert "**, including contracts that automatically renew after the expiry date,**".

Page 23, delete lines 3 through 4.

Page 23, line 5, delete "2." and insert "**1.**".

Page 23, line 6, delete "established under section 4 of" and insert "**created under**".

Page 23, line 7, delete "3." and insert "**2.**".

Page 23, delete lines 24 through 31.

Page 23, line 32, delete "5." and insert "**3.**".

Page 24, line 36, delete "6. (a) Before May 30, 2021," and insert "**4. (a) After May 30, 2021, but before June 15, 2021,**".

Page 24, line 41, delete "5" and insert "**3**".

Page 25, line 2, delete "forming" and insert "**informing**".

Page 25, line 21, delete "7." and insert "**5.**".

Page 25, line 37, after "carrier's" insert "**reasonable**".

Page 27, line 13, after "services" insert "**ordered, scheduled, or referred by a practitioner**".

Page 27, line 25, after "therapists);" insert "**or**".

Page 27, delete line 26.

Page 27, line 27, delete "(D)" and insert "**(C)**".

Page 27, delete line 28.

Page 27, between lines 30 and 31, begin a new paragraph and insert:

"**Sec. 9.5. As used in this chapter, "price" means the negotiated rate between the:**

(1) provider facility and practitioner; and

(2) covered individual's health carrier;

minus the amount that the health carrier will pay.".

Page 28, between lines 5 and 6, begin a new line block indented and insert:

"**(8) An infusion center that administers intravenous medications.**".

Page 28, line 25, after "each" insert "**scheduled**".

Page 28, line 29, delete "twenty-four (24) hours" and insert "**three (3) business days**".

Page 29, between lines 3 and 4, begin a new paragraph and insert:

"**(f) A practitioner and provider facility must provide a health carrier with timely information needed by the health carrier to comply with the requirements under this chapter.**".

Page 29, line 9, after "14." insert "**(a)**".

Page 29, between lines 32 and 33, begin a new paragraph and insert:

"**(b) A practitioner and provider facility must provide a health carrier with timely information needed by the health carrier comply to with the requirements under this chapter.**".

Page 29, line 34, delete "include on the Internet web" and insert "**ensure that the Internet web site includes a printed notice that:**

(1) is designed, lettered, and featured on the Internet web site so as to be conspicuous to and readable by any individual with normal vision who visits the Internet web site; and

(2) states the following, or words to the same effect: "A covered individual may at any time ask the health carrier for an estimate of the amount the health carrier will pay for or reimburse to a covered individual for nonemergency health care services that have been ordered for the covered individual or the nature and extent of the ordered nonemergency health care services a covered individual is entitled to receive from the health carrier. The law requires that an estimate be provided within 3 business days.".".

Page 29, delete lines 35 through 42.

Page 30, delete lines 1 through 4.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1005 as introduced.)

KIRCHHOFER

Committee Vote: yeas 8, nays 0.

HOUSE MOTION

Mr. Speaker: I move that House Bill 1005 be amended to read as follows:

Page 6, line 25, delete "(a)".

Page 6, delete lines 28 through 29.

Page 8, delete lines 39 through 40.

Page 18, delete lines 25 through 42.

Delete page 19.

Page 20, delete lines 1 through 3.

Page 40, between lines 6 and 7, begin a new paragraph and insert:

"SECTION 29. IC 27-8-11-13 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2021]: **Sec. 13. (a) A fully credentialed provider shall be reimbursed for eligible services provided at any in-network hospital if the following conditions are met:**

(1) The provider submits the documentation required by the insurer to be loaded under the provider group or hospital.

(2) The provider, provider group, or hospital is a network provider with the insurer.

(3) The services are provided in accordance with all terms and

conditions of the provider's, group provider's, or hospital's agreement or contract with the insurer.

(4) Prior authorization is obtained in accordance with IC 27-1-37.5 when required by the insurer for an eligible service.

(b) The insurer shall reimburse the provider or hospital for services described in subsection (a) at the rates determined by the contract between the provider and the insurer.

(c) An insurer is not required to credential a provider. However, if:

(1) a provider is employed by a hospital that is part of the hospital's network that is covered by the insurer; and

(2) the provider meets the insurer's credentialing requirements;

the insurer shall reimburse the provider for any reimbursable services from the date that the provider was employed by the hospital.

SECTION 30. IC 27-13-43-4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2021]: **Sec. 4. (a) A fully credentialed PROVIDER shall be reimbursed for eligible services provided at any in-network hospital if the following conditions are met:**

(1) The provider submits the documentation required by the health maintenance organization to be loaded under the provider group or hospital.

(2) The provider, provider group, or hospital is a network provider with the health maintenance organization.

(3) The services are provided in accordance with all terms and conditions of the provider's, group provider's, or hospital's agreement or contract with the health maintenance organization.

(4) Prior authorization is obtained in accordance with IC 27-1-37.5 when required by the health maintenance organization for an eligible service.

(b) The health maintenance organization shall reimburse the provider or hospital for services described in subsection (a) at the rates determined by the contract between the provider and the health maintenance organization.

(c) A health maintenance organization is not required to credential a provider. However, if:

(1) a provider is employed by a hospital that is part of the hospital's network that is covered by the health maintenance

organization; and

(2) the provider meets the health maintenance organization's credentialing requirements;

the health maintenance organization shall reimburse the provider for any reimbursable services from the date that the provider was employed by the hospital.".

Renumber all SECTIONS consecutively.

(Reference is to HB 1005 as printed January 24, 2020.)

LEHMAN

HOUSE MOTION

Mr. Speaker: I move that House Bill 1005 be amended to read as follows:

Page 6, between lines 8 and 9, begin a new paragraph and insert:

"SECTION 3. IC 16-18-2-46.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 46.5. "Canadian supplier", for purposes of IC 16-47-3, has the meaning set forth in IC 16-47-3-1.**".

Page 7, between lines 36 and 37, begin a new paragraph and insert:

"SECTION 15. IC 16-18-2-294.5, AS AMENDED BY P.L.208-2015, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 294.5. (a) "Program", for purposes of IC 16-40-4, has the meaning set forth in IC 16-40-4-3.

(b) "Program", for purposes of IC 16-41-7.5, has the meaning set forth in IC 16-41-7.5-2.

(c) "Program", for purposes of IC 16-47-1, has the meaning set forth in IC 16-47-1-3.

(d) "Program", for purposes of IC 16-47-3, has the meaning set forth in IC 16-47-3-2.".

Page 9, between lines 8 and 9, begin a new paragraph and insert:

"SECTION 17. IC 16-18-2-353.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: **Sec. 353.3. "Track-and-trace", for purposes of IC 16-47-3, has the meaning set forth in IC 16-47-3-3.**".

Page 9, between lines 13 and 14, begin a new paragraph and insert:

"SECTION 19. IC 16-18-2-363.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS

[EFFECTIVE JULY 1, 2020]: **Sec. 363.5. "Vendor", for purposes of IC 16-47-3, has the meaning set forth in IC 16-47-3-4.**".

Page 17, between lines 10 and 11, begin a new paragraph and insert:

"SECTION 24. IC 16-47-3 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 3. Importation of Prescription Drugs Program

Sec. 1. As used in this chapter, "Canadian supplier" means a:

(1) manufacturer;

(2) wholesale drug distributor; or

(3) pharmacy;

appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

Sec. 2. As used in this chapter, "program" refers to the importation of prescription drugs program established by section 5 of this chapter.

Sec. 3. As used in this chapter, "track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain, as described in Title II of the federal Drug Quality and Security Act (21 U.S.C. 351 et seq.).

Sec. 4. As used in this chapter, "vendor" means an entity that contracts with the state department to manage specified functions of the program.

Sec. 5. (a) The importation of prescription drugs program is established.

(b) The state department shall administer the program.

(c) The state department shall contract with a vendor to provide services under the program. The vendor must comply with the requirements of this chapter.

(d) The state department shall require a bond from the vendor to mitigate the financial consequences of potential acts of malfeasance or misfeasance, potential fraudulent acts, or potential dishonest acts committed by the vendor, an employee of the vendor, or a contractor or subcontractor of the vendor.

(e) Before July 1, 2021, the state department shall apply to the United States Department of Health and Human Services for approval of the program under 21 U.S.C. 384(1). The state department shall implement the program not later than six (6) months after the state department receives approval for the program. The request must include the following:

(1) A description of the state department's plan for operating the program.

(2) A demonstration of how the prescription drugs imported into Indiana under the program will meet the applicable federal and state standards for safety and effectiveness.

(3) A demonstration of how the prescription drugs imported into Indiana under the program will comply with federal track-and-trace procedures.

(4) A list of proposed prescription drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted.

(5) An estimate of the total cost savings attributable to the program.

(6) The costs of program implementation to the state.

(7) A list of potential Canadian suppliers from which the state would import the prescription drugs and a demonstration that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations, as well as all applicable federal and state laws and regulations.

(f) Upon receipt of federal approval of the program, the state department shall notify the following:

(1) The speaker of the house of representatives.

(2) The president pro tempore of the senate.

(3) The members of the health and provider services committee in the senate.

(4) The members of the public health committee in the house of representatives.

(g) Before the start of the general assembly session following receipt of the federal approval, the state department shall submit to the individuals described in subsection (f) a proposal for the implementation of funding of the program.

Sec. 6. (a) Before December 1, 2020, and by December 1 of each subsequent year, the vendor shall develop a wholesale prescription drug importation list identifying the prescription drugs that have the highest potential for cost savings to the state.

(b) In developing the list, the vendor shall consider at least the following in determining whether a prescription drug should be included on the list:

(1) Prescription drugs that, if included on the list, would provide the highest potential for cost savings in state administered programs.

(2) Prescription drugs for which there is a shortage in Indiana or the United States.

(3) Specialty prescription drugs.

(4) High volume prescription drugs.

(c) The state department shall review the wholesale prescription drug importation list at least every three (3) months to ensure that the list continues to meet the requirements of the program. The state department may direct the vendor to revise the list as necessary.

Sec. 7. (a) The vendor shall identify Canadian suppliers that:

(1) are in full compliance with:

(A) relevant Canadian federal and provincial laws and regulations; and

(B) the federal Drug Quality and Security Act;

(2) have agreed to export prescription drugs identified on the list described in section 6 of this chapter at prices that will provide cost savings to the state; and

(3) have obtained an international export pharmacy permit under IC 25-26-14.5.

(b) The vendor must verify that the Canadian suppliers meet all of the requirements of the program while meeting or exceeding the federal and state track-and-trace laws and regulations.

(c) The vendor shall:

(1) contract with an eligible Canadian supplier; or

(2) facilitate contracts between eligible importers and Canadian suppliers;

to import drugs under the program.

(d) The vendor shall maintain a list of all registered importers that participate in the program.

(e) The vendor shall ensure compliance with Title II of the federal Drug Quality and Security Act by all suppliers, importers, distributors, and participants in the program.

Sec. 8. (a) The vendor shall provide to the state department the following:

(1) An annual financial audit of the vendor's operations.

(2) Quarterly financial reports specific to the program, including information on the performance of the vendor and the vendor's subcontractors for the program.

(b) The state department shall determine the format and contents of the reports described in this section.

Sec. 9. (a) A Canadian supplier is eligible to participate in the program if the Canadian supplier meets the following requirements:

(1) Is in full compliance with relevant Canadian federal and provincial laws and regulations.

(2) Is identified by the vendor as eligible to participate in the program.

(3) Submits an attestation that the supplier has a registered agent in the United States, including the name and United States business address of the registered agent.

(b) An importer that meets the requirements of this chapter may import a prescription drug from an eligible Canadian supplier if the following conditions are met:

(1) The prescription drug meets the United States Food and Drug Administration's standards concerning safety, effectiveness, misbranding, and adulteration.

(2) The importation of the drug would not violate federal patent laws.

(3) The importation of the drug is expected to generate cost savings to the state.

(4) The drug is not any of the following:

(A) A controlled substance.

(B) A biological product.

(C) An infused drug.

(D) An intravenously injected drug.

(E) A drug that is inhaled during surgery.

(F) A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

Sec. 10. (a) The following entities may import prescription drugs under the program from a Canadian supplier that meets the requirements of this chapter:

(1) A pharmacist or wholesale drug distributor employed by or under contract with the state department for distribution to a county health department for dispensing to the patients of the county health department.

(2) A pharmacist or wholesale drug distributor employed by or under contract with a pharmacy that is a Medicaid provider, for dispensing to the pharmacy's Medicaid recipients.

(3) A pharmacist or wholesale drug distributor employed by or under contract with the department of correction, for dispensing to inmates in the custody of the department of correction.

(b) A Canadian supplier that meets the requirements of this chapter and an eligible importer described in subsection (a) that is

participating in the program:

(1) must comply with all track-and-trace requirements; and

(2) may not distribute, dispense, or sell prescription drugs imported under this program outside Indiana.

Sec. 11. (a) The vendor shall ensure the safety and quality of drugs imported under the program.

(b) The vendor shall do the following:

(1) For an initial imported shipment of a specific drug by an importer, ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with federal law.

(2) For every subsequent imported shipment of that drug by that importer, ensure that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with federal law.

(3) Certify that the drug:

(A) is approved for marketing in the United States and is not adulterated or misbranded; and

(B) meets all of the labeling requirements under 21 U.S.C. 352.

(4) Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

(5) Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with federal and state laws and regulations governing laboratory qualifications.

(c) All testing required by this section must be conducted in a qualified laboratory that meets the standards under federal and state laws and regulations governing laboratory qualifications for drug testing.

(d) The vendor shall maintain information and documentation submitted under this section for at least seven (7) years.

Sec. 12. An importer participating in the program must submit all of the following information to the vendor concerning drugs provided for the program:

(1) The name and quantity of the active ingredients of the drug.

(2) A description of the dosage form of the drug.

(3) The date on which the drug is received.

(4) The quantity of the drug that is received.

(5) The point of origin and destination of the drug.

(6) The price paid by the importer for the drug.

Sec. 13. (a) A Canadian supplier participating in the program must submit the following information and documentation to the vendor specifying all of the following concerning drugs provided for the program:

(1) The original source of the drug, including:

(A) the name of the manufacturer of the drug;

(B) the date on which the drug was manufactured; and

(C) the location, including the country, state or province, and city, where the drug was manufactured.

(2) The date on which the drug is shipped.

(3) The quantity of the drug that is shipped.

(4) The quantity of each lot of the drug originally received and the source of the lot.

(5) The lot or control number and the batch number assigned to the drug by the manufacturer.

(b) The state department may require that the vendor collect additional information from the Canadian supplier that is necessary to ensure the protection of the public health.

Sec. 14. (a) The state department shall immediately suspend the importation of a specific drug or the importation of drugs by a specific importer if the state department discovers that any drug or importer activity is in violation of this chapter or any federal or state law or regulation.

(b) The state department may revoke the suspension under subsection (a) of the importation of a specific drug or the importation of drugs by a specific importer if the state department determines that the public is adequately protected from counterfeit or unsafe drugs being imported into Indiana.

Sec. 15. Before December 1 of each year, the state department shall submit a report to the governor and the general assembly in an electronic format under IC 5-14-6 on the operation of the program during the previous fiscal year. The report must include at least the following:

(1) A list of the prescription drugs that were imported under the program.

(2) The number of participating persons.

(3) The number of prescriptions dispensed through the program.

(4) The estimated cost savings to the state during the previous fiscal year and to date that are attributable to the program.

(5) A description of the methodology used to determine which

drugs should be included on the wholesale prescription drug importation list.

(6) Documentation on how the program ensures the following:

(A) Canadian suppliers participating in the program are of high quality and high performance and in full compliance with relevant:

(i) Canadian federal and provincial laws and regulations; and

(ii) federal and state laws, regulations, and rules.

(B) Prescription drugs imported under the program are not shipped, sold, or dispensed outside Indiana once in the possession of the importer.

(C) Prescription drugs imported under the program are pure, unadulterated, potent, and safe.

(D) The program does not place consumers at a higher health and safety risk than if the consumers did not participate.

(E) The program provides cost savings to the state on imported prescription drugs.

Sec. 16. The state department shall adopt rules under IC 4-22-2 necessary to implement this chapter.".

Page 24, after line 42, begin a new paragraph and insert:

"SECTION 26. IC 25-26-13-4, AS AMENDED BY P.L.5-2016, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 4. (a) The board may:

(1) adopt rules under IC 4-22-2 for implementing and enforcing this chapter;

(2) establish requirements and tests to determine the moral, physical, intellectual, educational, scientific, technical, and professional qualifications for applicants for pharmacists' licenses;

(3) refuse to issue, deny, suspend, or revoke a license or permit or place on probation or fine any licensee or permittee under this chapter;

(4) regulate the sale of drugs and devices in the state of Indiana;

(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or

their representatives from entering such places and making such inspections;

(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;

(7) subject to IC 25-1-7, investigate complaints, subpoena witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;

(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; and

(9) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter.

(b) The board shall adopt rules under IC 4-22-2 for the following:

(1) Establishing standards for the competent practice of pharmacy.

(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.

(3) Establishing standards and procedures before January 1, 2006, to ensure that a pharmacist:

(A) has entered into a contract that accepts the return of expired drugs with; or

(B) is subject to a policy that accepts the return of expired drugs of;

a wholesaler, manufacturer, or agent of a wholesaler or manufacturer concerning the return by the pharmacist to the wholesaler, the manufacturer, or the agent of expired legend drugs or controlled drugs. In determining the standards and procedures, the board may not interfere with negotiated terms related to cost, expenses, or reimbursement charges contained in contracts between parties, but may consider what is a reasonable quantity of a drug to be purchased by a pharmacy. The standards and procedures do not apply to vaccines that prevent influenza, medicine used for the treatment of malignant hyperthermia, and other drugs determined by the board to not be subject to a return policy. An agent of a wholesaler or manufacturer must be appointed in writing and have policies, personnel, and facilities to handle properly returns of expired legend drugs and controlled substances.

(4) The following concerning the issuance of a permit under

IC 25-26-14.5:

(A) Inspection report requirements described under IC 25-26-14.5-1.

(B) The financial responsibility of entities that hold any permit under IC 25-26-14.5.

(c) The board may grant or deny a temporary variance to a rule it has adopted if:

(1) the board has adopted rules which set forth the procedures and standards governing the grant or denial of a temporary variance; and

(2) the board sets forth in writing the reasons for a grant or denial of a temporary variance.

(d) The board shall adopt rules and procedures, in consultation with the medical licensing board, concerning the electronic transmission of prescriptions. The rules adopted under this subsection must address the following:

(1) Privacy protection for the practitioner and the practitioner's patient.

(2) Security of the electronic transmission.

(3) A process for approving electronic data intermediaries for the electronic transmission of prescriptions.

(4) Use of a practitioner's United States Drug Enforcement Agency registration number.

(5) Protection of the practitioner from identity theft or fraudulent use of the practitioner's prescribing authority.

(e) The governor may direct the board to develop:

(1) a prescription drug program that includes the establishment of criteria to eliminate or significantly reduce prescription fraud; and

(2) a standard format for an official tamper resistant prescription drug form for prescriptions (as defined in IC 16-42-19-7(1)).

The board may adopt rules under IC 4-22-2 necessary to implement this subsection.

(f) The standard format for a prescription drug form described in subsection (e)(2) must include the following:

(1) A counterfeit protection bar code with human readable representation of the data in the bar code.

(2) A thermochromic mark on the front and the back of the prescription that:

(A) is at least one-fourth (1/4) of one (1) inch in height and width; and

(B) changes from blue to clear when exposed to heat.

(g) The board may contract with a supplier to implement and

manage the prescription drug program described in subsection (e). The supplier must:

(1) have been audited by a third party auditor using the SAS 70 audit or an equivalent audit for at least the three (3) previous years; and

(2) be audited by a third party auditor using the SAS 70 audit or an equivalent audit throughout the duration of the contract;

in order to be considered to implement and manage the program.

(h) The board shall adopt rules under IC 4-22-2, or emergency rules in the manner provided under IC 4-22-2-37.1 that take effect on July 1, 2016, concerning:

(1) professional determinations made under IC 35-48-4-14.7(d); and

(2) the determination of a relationship on record with the pharmacy under IC 35-48-4-14.7.

(i) The board may:

(1) review professional determinations made by a pharmacist; and

(2) take appropriate disciplinary action against a pharmacist who violates a rule adopted under subsection (h) concerning a professional determination made;

under IC 35-48-4-14.7 concerning the sale of ephedrine and pseudoephedrine.

SECTION 27. IC 25-26-13-29, AS AMENDED BY P.L.209-2018, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 29. (a) It is unlawful:

(1) For any person to display or permit to be displayed, a pharmacy permit in any facility or place of business other than that for which it was issued.

(2) For any person to accept a prescription for filling or compounding at any place or facility for which there is not a valid pharmacy permit.

(3) For any person to operate a pharmacy or to take, assume, exhibit, display, or advertise by any medium, the title "drugs", "prescriptions", "medicine", "drug store", "pharmacy", or "apothecary shop", or any combination of such titles or any other title, symbol, term, or description of like import intended to cause the public to believe that it is a pharmacy unless the person holds a valid pharmacy permit.

(4) For any person to engage or offer to engage in the practice of pharmacy or to hold himself or herself out as a pharmacist without a valid pharmacist's license that is classified as active by the board.

(b) A person who violates a provision of subsection (a) commits a Level 6 felony.

(c) Nothing in this chapter shall apply to, nor in any manner interfere with the business of a general merchant in selling and distributing nonnarcotic, nonprescription medicines or drugs which are prepackaged, fully prepared by the manufacturer for use by the consumer, and labeled in accordance with the requirements of the state and federal food and drug acts.

(d) This chapter does not apply to, or in any manner interfere with, the business of a manufacturer in selling and delivering a dialysate drug or a device that is necessary for home peritoneal renal dialysis for a patient who has end stage renal disease if all of the following apply:

(1) The dialysate drug or device is approved by the federal Food and Drug Administration under federal law.

(2) The dialysate drug or device is held by the manufacturer, a third party logistics provider, or a wholesale drug distributor in accordance with the requirements of IC 25-26-14.

(3) The dialysate drug or device is delivered in the manufacturer's original, sealed packaging.

(4) The dialysate drug or device is delivered only upon:

(A) receipt of a physician's prescription by a pharmacy that holds a pharmacy permit under this chapter; and

(B) the transmittal of an order from the pharmacy described in clause (A) to the manufacturer, third party logistics provider, or wholesale drug distributor.

(5) The manufacturer, third party logistics provider, or wholesale drug distributor delivers the dialysate drug or device directly to:

(A) the patient or the patient's designee for self-administration of the dialysis therapy; or

(B) a health care provider for administration of the dialysis therapy to the patient.

(e) This chapter does not apply to the purchase of prescription drugs through and in compliance with the importation of prescription drugs program established under IC 16-47-3.

SECTION 28. IC 25-26-14-17.8, AS AMENDED BY P.L.98-2006, SECTION 22, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]: Sec. 17.8. (a) **This section does not apply to purchase of prescription drugs through and in compliance with the importation of prescription drugs program established under IC 16-47-3.** A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required

under this section and rules adopted by the board. However, the due diligence requirements of this section do not apply to purchases from an unlicensed wholesale drug distributor that has obtained accreditation through the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors program.

(b) Before the initial purchase of legend drugs from the unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall obtain the following information from the unlicensed wholesale drug distributor:

(1) A list of states in which the unlicensed wholesale drug distributor is licensed.

(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.

(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.

(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.

(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.

(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.

(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.

(8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.

(9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.

(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.

(11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.

(13) A statement:

(A) as to whether; and

(B) of the identity of each manufacturer for which;

the unlicensed wholesale drug distributor is an authorized

distributor.

(c) Before the initial purchase of legend drugs from an unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall:

(1) request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department of all individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and

(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years after a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs from the unlicensed wholesale drug distributor; and

(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall ensure that the unlicensed wholesale drug distributor maintains a record keeping system that meets the requirements of section 17(3) of this chapter.

(f) If a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor has reason to believe that a legend drug purchased from the unlicensed wholesale drug distributor is misbranded, adulterated, counterfeit, or suspected counterfeit, the licensed wholesale drug distributor shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug for which a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) shall provide, upon request, detailed information regarding the

distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and any electronic mail address of the unlicensed wholesale drug distributor that sold the legend drug.

(h) If a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) and is unable to authenticate each distribution of the legend drug, the licensed wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration within ten (10) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

(l) If a wholesale drug distributor conducts a random authentication under subsection (j) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 29. IC 25-26-14.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 14.5. International Export Pharmacy Permit and Wholesale Drug Distributor Permit

Sec. 1. (a) To participate as an exporter of prescription drugs into Indiana under the importation of prescription drugs program established by IC 16-47-3-5, a pharmacy located outside the United States must meet the following requirements:

(1) Hold an international export pharmacy permit issued under this chapter.

(2) Maintain at all times an active and unencumbered license or permit to operate a pharmacy:

(A) in compliance with the laws and rules of the jurisdiction in which the pharmacy is located and from which the prescription drugs will be exported; and

(B) in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(3) Submit an application for an international export pharmacy permit on a form developed and provided by the board.

(b) An applicant for an international export pharmacy permit must submit the following to the board with the application required under subsection (a)(3):

(1) Proof of an active and unencumbered license or permit to operate a pharmacy in compliance with the laws and rules of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported.

(2) Documentation demonstrating that the country in which the pharmacy operates has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(3) The location, names, and title of all principal corporate officers and the pharmacist who serves as the prescription department manager for prescription drugs exported into Indiana under the importation of prescription drugs program.

(4) A written attestation by an owner or officer of the applicant and by the applicant's prescription drug manager containing the following affirmations:

(A) That the individual has read and understands the laws and rules governing the manufacture, distribution, and dispensing of prescription drugs in Indiana.

(B) That prescription drugs shipped, mailed, or delivered into Indiana:

(i) will meet or exceed Indiana's standards for safety and

efficacy; and

(ii) will not have been, and may not be, manufactured or distributed in violation of the laws and rules of the jurisdiction in which the applicant is located and from which the prescription drugs will be exported.

(5) A current inspection report from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located. The inspection report must reflect compliance with this section. An inspection report is current if the inspection was conducted not earlier than six (6) months before the submission of the application for an initial permit or not earlier than one (1) year for the renewal of a permit.

(c) If an applicant is not able to submit an inspection report that meets the requirements of subsection (b)(5), the board must do one (1) of the following:

(1) Conduct, or contract with a person to conduct, an onsite inspection at the cost of the applicant.

(2) Accept a current inspection report from an entity that:

(A) meets requirements adopted by the board under IC 4-22-2 for entities to perform inspections; and

(B) has been approved by the board.

(3) Accept a current inspection report from the United States Food and Drug Administration conducted under the federal Drug Quality and Security Act.

Sec. 2. To participate as an exporter of prescription drugs into Indiana under the importation of prescription drugs program established by IC 16-47-3, a nonresident prescription drug manufacturer located outside the United States must register with the board and obtain the international export pharmacy permit under this chapter.

Sec. 3. (a) The board shall adopt rules under IC 4-22-2 governing the financial responsibility of a pharmacy that holds a permit under this chapter. The rules must include at least the following:

(1) Financial reporting requirements.

(2) Standards for financial capability to perform the functions governed by the permit.

(3) Requirements for ensuring that the permit holder and the permit holder's contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest acts committed by the

permit holder or the permit holder's contractors.

(b) The board shall adopt rules under IC 4-22-2 concerning inspection report requirements described in section 1 of this chapter.

Sec. 4. (a) A wholesale drug distributor located outside the United States must obtain an international prescription drug wholesale drug distributor permit under this chapter to engage in the wholesale exportation and distribution of prescription drugs in Indiana under the importation of prescription drugs program established by IC 16-47-3-5.

(b) A wholesale drug distributor must meet the following in order to obtain a wholesale drug distributor permit:

(1) Be licensed or permitted to operate in a country with which the United States has:

(A) a current mutual recognition agreement;

(B) a current cooperation agreement;

(C) a current memorandum of understanding; or

(D) another federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(2) Maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with the laws and rules of the jurisdiction in which the wholesale drug distributor operates.

(c) The board shall adopt rules under IC 4-22-2 governing the financial responsibility of a wholesale drug distributor that holds a permit under this chapter. The rules must include at least the following:

(1) Financial reporting requirements.

(2) Standards for financial capability to perform the functions governed by the permit.

(3) Requirements for ensuring that a wholesale drug distributor holding a permit under this chapter and the wholesale drug distributor's contractors are held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest acts committed by the permit holder or the permit holder's contractors.".

Renumber all SECTIONS consecutively.

(Reference is to HB 1005 as printed January 24, 2020.)

HATFIELD