April 2, 2021

ENGROSSED
HOUSE BILL No. 1468

DIGEST OF HB 1468 (Updated March 31, 2021 2:15 pm - DI 104)

Citations Affected: IC 12-7; IC 12-21; IC 25-1; IC 25-26; IC 27-1.

Synopsis: Various health matters. Specifies that the division of mental health and addiction (division) has primary oversight over suicide prevention and crisis services activities and coordination and designation of the 9-8-8 crisis hotline centers. Sets forth requirements to be designated as a 9-8-8 crisis hotline center. Establishes the statewide 9-8-8 trust fund. Delays the requirement that a prescription for a controlled substance be in an electronic format until January 1, 2022. Allows for an exemption from the requirement of issuing a controlled substance prescription in an electronic format if the dispensing pharmacy or provider is unable to receive or process an electronically transmitted prescription. Requires certain rules adopted by the Indiana board of pharmacy (board) to be substantially similar to certain federal regulations. Allows a pharmacist and pharmacy technician to administer an immunization for coronavirus disease.
(Continued next page)

Effective: Upon passage; December 31, 2020 (retroactive); July 1, 2021.

Davisson, Clere

(SENATE SPONSORS — CRIDER, CHARBONNEAU, BECKER, GROOMS)

January 14, 2021, read first time and referred to Committee on Public Health.
February 15, 2021, amended, reported — Do Pass.
February 17, 2021, read second time, ordered engrossed. Engrossed.
February 22, 2021, read third time, passed. Yeas 95, nays 0.

SENATE ACTION
March 2, 2021, read first time and referred to Committee on Health and Provider Services.
April 1, 2021, amended, reported favorably — Do Pass.

Digest Continued

Allows a registered nurse to provide for the direct supervision of a pharmacist intern or pharmacist student who administers an immunization. Changes references of the pharmacist in charge to the pharmacist on duty. Allows a pharmacist to supervise eight pharmacy interns. Allows a pharmacy technician to work remotely to perform specified responsibilities. Provides that the board shall hold the pharmacy permit holder accountable, rather than the qualifying pharmacy, for staffing violations if the qualifying pharmacist does not have the authority to make staffing determinations. Specifies that a transfer of a prescription includes a schedule II controlled substance. Removes the requirement that a pharmacist provide a patient with a written advance beneficiary notice that states that the patient may not be eligible for reimbursement for the device or supply. Changes remote dispensing facility requirements concerning location of the facility. Changes how long a remote dispensing facility must retain a surveillance recording from 45 days to 30 days. Removes specified physical requirements that a video monitor being used by the remote facility must meet. Adds therapeutic substitution to the definition of protocol for purposes of drug regimen adjustments and defines "therapeutic alternative" and specifies use of therapeutic alternative requirements for protocols. Removes a requirement for drug protocols concerning availability of medical records. Allows for physician assistants and advance practice registered nurses to make referrals to pharmacists. Adds any plan or program that provides payment, reimbursement, or indemnification for the cost of prescription drugs to the definition of a "health plan".

April 2, 2021

First Regular Session of the 122nd General Assembly (2021)

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 2020 Regular Session of the General Assembly.

ENGROSSED
HOUSE BILL No. 1468

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 12-7-2-0.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: **Sec. 0.3. "9-8-8 crisis hotline center", for purposes of IC 12-21-8, has the meaning set forth in IC 12-21-8-1.**

SECTION 2. IC 12-7-2-51.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: **Sec. 51.6. "Crisis receiving and stabilization services", for purposes of IC 12-21-8, has the meaning set forth in IC 12-21-8-2.**

SECTION 3. IC 12-7-2-131.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: **Sec. 131.4. "Mobile crisis team", for purposes of IC 12-21-8, has the meaning set forth in IC 12-21-8-3.**

SECTION 4. IC 12-7-2-131.9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: **Sec. 131.9. "National suicide**

prevention lifeline", for purposes of IC 12-21-8, has the meaning set forth in IC 12-21-8-4.

SECTION 5. IC 12-7-2-136.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: **Sec. 136.8. "Peer", for purposes of IC 12-21-8, has the meaning set forth in IC 12-21-8-5.**

SECTION 6. IC 12-21-8 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]:

Chapter 8. 9-8-8 Crisis Hotline Centers and Mobile Crisis Teams

Sec. 1. As used in this chapter, "9-8-8 crisis hotline center" or "center" means a state identified center participating in the national suicide prevention lifeline network to respond to statewide or regional 9-8-8 calls.

Sec. 2. As used in this chapter, "crisis receiving and stabilization services" means behavioral health services that provide short term, less than twenty-four (24) hour care with the capacity for diagnosis, initial management, observation, crisis stabilization, and follow-up referral services to a person in a homelike environment.

Sec. 3. As used in this chapter, "mobile crisis team" means behavioral health professionals and peers that provide professional onsite community based intervention, including de-escalation, stabilization, and treatment for individuals who are experiencing a behavioral health crisis.

Sec. 4. As used in this chapter, "national suicide prevention lifeline" means a nationally certified network of local crisis centers that provide free and confidential emotional support to people in suicidal crisis or emotional distress on a twenty-four (24) hours a day, seven (7) days a week basis.

Sec. 5. As used in this chapter, "peer" means an individual employed on the basis of the individual's personally lived experience with mental illness or addiction and recovery and meets the requirements of peer certification established by the division.

Sec. 6. (a) The division has primary oversight over suicide prevention and crisis services activities and essential coordination with designated 9-8-8 crisis hotline centers. The division shall work with the national suicide prevention lifeline and the Veterans Crisis Hotline networks for the purpose of ensuring consistency of public messaging concerning 9-8-8 services.

(b) Not later than July 1, 2022, the division may designate at least one (1) 9-8-8 crisis hotline center in Indiana to coordinate

crisis intervention services and crisis care coordination to individuals accessing the 9-8-8 suicide prevention and behavioral health crisis hotline (9-8-8 crisis hotline) from anywhere in Indiana twenty-four (24) hours a day, seven (7) days a week.

(c) In order to be designated by the division under subsection (b), a 9-8-8 crisis hotline must meet the following:

(1) Have an active agreement with the administrator of the national suicide prevention lifeline for participation within the network.

(2) Comply with the national suicide prevention lifeline requirements and best practice guidelines for operational and clinical standards.

(3) Use technology, including chat and texting that is interoperable between and across crisis and emergency response systems used throughout Indiana to ensure cohesive and coordinated crisis care.

Sec. 7. The division shall adopt rules under IC 4-22-2 to allow appropriate information sharing and communication between and across crisis and emergency response systems for the purpose of real time crisis care coordination, including deployment of crisis and outgoing services and linked, flexible services specific to crisis response.

Sec. 8. (a) A designated 9-8-8 crisis hotline center may deploy crisis and outgoing services, including mobile crisis teams, and coordinate access to crisis receiving and stabilization services or other appropriate local sources in accordance with guidelines by the national suicide prevention lifeline.

(b) A designated 9-8-8 crisis hotline shall coordinate access to crisis receiving and stabilization services for individuals accessing the 9-8-8 suicide prevention and behavioral health crisis hotline through appropriate information sharing concerning availability of services.

(c) A designated 9-8-8 crisis hotline center shall meet the requirements set forth by the national suicide prevention lifeline for serving high risk and specialized populations, including individuals with co-occurring mental health and substance use disorders and other relevant and culturally sensitive special populations, as identified by the federal Substance Abuse and Mental Health Services Administration, including training requirements and policies for transferring callers to an appropriate specialized center or subnetwork.

(d) A designated 9-8-8 crisis hotline center must provide

follow-up services to individuals accessing the 9-8-8 crisis hotline consistent with guidelines and policies established by the national suicide prevention lifeline.

Sec. 9. Before March 1 of each year, a designated 9-8-8 crisis hotline center shall submit a written report to the division concerning the 9-8-8 crisis hotline's usage and the services provided by the center.

Sec. 10. (a) The division shall coordinate:

(1) available onsite response services of crisis calls using state and locally funded mobile crisis teams; and

(2) crisis receiving and stabilization services resulting from a 9-8-8 call.

(b) The mobile crisis teams must include the following:

(1) Jurisdiction based behavioral health teams, including:

(A) a behavioral health professional licensed under IC 25-23.6; and

(B) peers certified by the division.

(2) Emergency medical services personnel licensed under IC 16-31.

(3) Law enforcement based coresponder behavioral health teams.

Sec. 11. (a) The statewide 9-8-8 trust fund is established for purposes of creating and maintaining a statewide 9-8-8 suicide prevention and mental health crisis system described in this chapter. The fund shall be administered by the division.

(b) The expenses of administering the fund shall be paid from money in the fund.

(c) The treasurer of the state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested. Interest that accrues from the investments shall be deposited in the fund.

(d) The fund shall consist of the following:

(1) Appropriations made to the fund by the general assembly.

(2) Funds received from the federal government for the support of 9-8-8 services in Indiana.

(3) Investment earnings, including interest, on money in the fund.

(4) Money from any other source, including gifts and grants.

(e) Money in the fund at the end of a state fiscal year does not revert to the state general fund and is not subject to transfer to any other fund for any other use or purpose outside of those specified in this section.

Sec. 12. The division may adopt rules under IC 4-22-2 to implement and administer this chapter.

SECTION 7. IC 25-1-9.3-7, AS ADDED BY P.L.28-2019, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE DECEMBER 31, 2020 (RETROACTIVE)]: Sec. 7. After ~~December 31, 2020,~~ **December 31, 2021,** except as provided in section 8 of this chapter, a prescriber shall issue a prescription for a controlled substance:

(1) in an electronic format; and

(2) by electronic transmission from the prescriber to a pharmacy;

in accordance with rules adopted by the board under IC 25-26-13-4(d).

SECTION 8. IC 25-1-9.3-8, AS AMENDED BY P.L.114-2020, SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE DECEMBER 31, 2020 (RETROACTIVE)]: Sec. 8. **Beginning January 1, 2022,** a prescriber may issue a prescription for a controlled substance in a written format, a faxed format, or an oral order if any of the following apply:

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

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

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

(C) the inability of the dispensing pharmacy or provider to receive or process an electronically transmitted prescription.

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

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

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

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

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

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

(i) a standing order;
(ii) approved protocol for drug therapy;
(iii) collaborative drug management; or
(iv) comprehensive medication management.

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

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

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

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

SECTION 9. IC 25-1-9.3-9, AS AMENDED BY P.L.114-2020, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 9. (a) The board shall, in consultation with the medical licensing board, adopt rules under IC 4-22-2 to implement this chapter, including:

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

(A) economic hardship;

(B) technological limitations outside the control of the prescriber **that are not otherwise specified in section 8 of this chapter;** or

(C) other circumstances determined by the board; and

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

(b) Any rules adopted under this chapter must be substantially similar to the requirements and exceptions under:

(1) 42 U.S.C. 1395w-104; **and**

(2) any regulations adopted under 42 U.S.C. 1395w-104.

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

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

(2) July 1, 2023.

(d) A provision described in:

(1) section 8(1) through 8(4);

(2) section 8(6); and

(3) section 8(7);

of this chapter does not require a waiver of any rule adopted under this chapter.

SECTION 10. IC 25-26-13-2, AS AMENDED BY P.L.89-2015, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 2. As used in this chapter:

"Administering" means the direct application of a drug to the body of a person by injection, inhalation, ingestion, or any other means.

"Board" means the Indiana board of pharmacy.

"Controlled drugs" are those drugs on schedules I through V of the federal Controlled Substances Act or on schedules I through V of IC 35-48-2.

"Coronavirus disease" means the disease caused by the severe acute respiratory syndrome coronavirus 2 virus (SARS-CoV-2).

"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

"Dispensing" means issuing one (1) or more doses of a drug in a suitable container with appropriate labeling for subsequent administration to or use by a patient.

"Drug" means:

(1) articles or substances recognized in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them;

(2) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) articles other than food intended to affect the structure or any function of the body of man or animals; or

(4) articles intended for use as a component of any article specified in subdivisions (1) through (3) and devices.

"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order

shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in quantity or days; adequate directions for the proper use of the drug or device when it is administered to the patient; and the name of the prescriber.

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, which is:

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Electronic data intermediary" means an entity that provides the infrastructure that connects a computer system or another electronic device used by a prescribing practitioner with a computer system or another electronic device used by a pharmacy to facilitate the secure transmission of:

(1) an electronic prescription order;

(2) a refill authorization request;

(3) a communication; and

(4) other patient care information;

between a practitioner and a pharmacy.

"Electronic signature" means an electronic sound, symbol, or process:

(1) attached to or logically associated with a record; and

(2) executed or adopted by a person;

with the intent to sign the record.

"Electronically transmitted" or "electronic transmission" means the transmission of a prescription in electronic form. The term does not include the transmission of a prescription by facsimile.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Medication therapy management" means a distinct service or group of services that optimize therapeutic outcomes for individuals that are independent of, but may occur in conjunction with, the provision of a medication or medical device. The term includes the following services:

(1) Performing or obtaining assessments of an individual's health status.

(2) Formulating a medication treatment plan.

(3) Selecting, initiating, modifying, or administering medication therapy.

(4) Monitoring and evaluating an individual's response to therapy, including safety and effectiveness.

(5) Performing a comprehensive medication review to identify, resolve, and prevent medication related problems, including adverse drug events.

(6) Documenting the care delivered and communicating essential information to the patient's other health care providers.

(7) Providing education and training designed to enhance patient understanding and appropriate use of the individual's medications.

(8) Providing information and support services and resources designed to enhance patient adherence with the individual's therapeutic regimens, including medication synchronization.

(9) Coordinating and integrating medication therapy management

services within the broader health care services being provided to an individual.

(10) Providing other patient care services allowable by law.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" has the meaning set forth in IC 16-42-19-5.

"Pharmacist" means a person licensed under this chapter.

"Pharmacist intern" means a person who is:

(1) permitted by the board to engage in the practice of pharmacy while under the personal supervision of a pharmacist and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) a graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate and who is permitted by the board to obtain practical experience as a requirement for licensure as a pharmacist;

(3) a qualified applicant awaiting examination for licensure; or

(4) an individual participating in a residency or fellowship program.

"Pharmacy" means any facility, department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern or an unlicensed person under section 18.5 of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug order or sold or given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist under this article.

(8) Provision of medication therapy management.

"Prescription" means a written order or an order transmitted by other means of communication from a practitioner to or for an ultimate user for any drug or device containing:

(1) the name and address of the patient;

(2) the date of issue;

(3) the name and strength or size (if applicable) of the drug or device;

(4) the amount to be dispensed (unless indicated by directions and duration of therapy);

(5) adequate directions for the proper use of the drug or device by the patient;

(6) the name of the practitioner; and

(7) if the prescription:

(A) is in written form, the signature of the practitioner; or

(B) is in electronic form, the electronic signature of the practitioner.

"Qualifying pharmacist" means the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operations of the pharmacy under the permit.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents, or objects

which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

SECTION 11. IC 25-26-13-10.5, AS ADDED BY P.L.98-2006, SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 10.5. (a) A pharmacy intern may engage in the practice of pharmacy if the activities are under the direct supervision of a pharmacist. The pharmacist ~~in charge~~ **on duty** is responsible for the activities relating to the practice of pharmacy performed by the pharmacy intern.

(b) A pharmacist shall review in person the prescription drug order and the dispensed product prepared by a pharmacy intern before the product is dispensed to the patient or the patient's agent.

SECTION 12. IC 25-26-13-18.5, AS AMENDED BY P.L.202-2017, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 18.5. (a) As used in this section, "immediate and personal supervision" means within reasonable visual and vocal distance of the pharmacist.

(b) Except as provided in ~~subsection~~ **subsections** (d) **and (e),** licensed pharmacy technicians or pharmacy technicians in training who are:

(1) licensed or certified under IC 25-26-19; and

(2) practicing at a pharmacy;

must practice under a licensed pharmacist's immediate and personal supervision at all times.

(c) A pharmacist may not supervise more than ~~six (6)~~ **eight (8)** pharmacy interns, pharmacy technicians, or pharmacy technicians in training at any time. Not more than three (3) of the ~~six (6)~~ **eight (8)** individuals being supervised by a pharmacist may be pharmacy technicians in training.

(d) A licensed pharmacy technician employed at a remote dispensing facility (as defined in IC 25-26-13.5-3) may be under the supervision of a pharmacist through the use of a computer link, a video link, and an audio link.

(e) A pharmacy technician may work remotely for nondispensing job responsibilities, including:

(1) data entry;

(2) insurance processing; or

(3) other responsibilities that do not require the pharmacy technician to be physically present at the pharmacy.

SECTION 13. IC 25-26-13-20, AS AMENDED BY P.L.152-2012, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 20. (a) A person desiring to open, establish, operate, or maintain a pharmacy shall apply to the board for a pharmacy permit on a form provided by the board. The applicant shall set forth:

(1) the name and occupation of the persons desiring the permit;

(2) the location, including street address and city, of the pharmacy;

(3) the name of the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operation of the pharmacy under the permit; and

(4) such other information as the board may require.

(b) If the applicant desires to open, establish, operate, or maintain more than one (1) pharmacy, the applicant must file a separate application for each. Each pharmacy must be qualified by a different pharmacist.

(c) The board shall permit a pharmacist to serve as a qualifying pharmacist for more than one (1) pharmacy holding a Category II pharmacy permit upon the holder of the Category II permit showing circumstances establishing that:

(1) the permit holder has made a reasonable effort, without success, to obtain a qualifying pharmacist who is not serving as a qualifying pharmacist at another Category II pharmacy; and

(2) the single pharmacist could effectively fulfill all duties and responsibilities of the qualifying pharmacist at both locations.

However, the board shall hold the permit holder responsible and may not discipline or otherwise hold the qualifying pharmacist responsible for staffing deficiencies of the pharmacy if the qualifying pharmacist does not have authority for staffing determinations of the pharmacy.

(d) The board shall grant or deny an application for a permit not later than one hundred twenty (120) days after the application and any additional information required by the board are submitted.

(e) The board may not issue a pharmacy permit to a person who desires to operate the pharmacy out of a residence.

SECTION 14. IC 25-26-13-24.8, AS AMENDED BY P.L.114-2020, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE

JULY 1, 2021]: Sec. 24.8. (a) Upon request of a patient, a pharmacy shall transfer to another pharmacy a prescription for the patient, **including a prescription for a schedule II controlled substance,** that the pharmacy has received but not filled unless:

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

(2) otherwise prohibited by federal law.

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

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

SECTION 15. IC 25-26-13-31, AS AMENDED BY P.L.114-2020, SECTION 13, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 31. (a) A pharmacist may do the following:

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

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

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

(4) Participate in drug or drug related research.

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

(A) Inhalation spacer.

(B) Nebulizer.

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

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

(E) Diabetes blood sugar testing supplies.

(F) Pen needles.

(G) Syringes for medication use.

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

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

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

SECTION 16. IC 25-26-13-31.2, AS AMENDED BY P.L.202-2017, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 31.2. (a) A pharmacist may administer an immunization to an individual under a drug order or prescription.

(b) Subject to subsection (c), a pharmacist may administer immunizations for the following to a group of individuals under a drug order, under a prescription, or according to a protocol approved by a physician:

(1) Influenza.
(2) Shingles (herpes zoster).
(3) Pneumonia.
(4) Tetanus, diphtheria, and acellular pertussis (whooping cough).
(5) Human papillomavirus (HPV) infection.
(6) Meningitis.
(7) Measles, mumps, and rubella.
(8) Varicella.
(9) Hepatitis A.
(10) Hepatitis B.
(11) Haemophilus influenzae type b (Hib).
(12) Coronavirus disease.

(c) A pharmacist may administer an immunization under subsection (b) if the following requirements are met:

(1) The physician specifies in the drug order, prescription, or protocol the group of individuals to whom the immunization may be administered.
(2) The physician who writes the drug order, prescription, or protocol is licensed and actively practicing with a medical office in Indiana and not employed by a pharmacy.
(3) The pharmacist who administers the immunization is responsible for notifying, not later than fourteen (14) days after the pharmacist administers the immunization, the physician who authorized the immunization and the individual's primary care physician that the individual received the immunization.
(4) If the physician uses a protocol, the protocol may apply only to an individual or group of individuals who:
(A) except as provided in clause (B), are at least eleven (11) years of age; or
(B) for the pneumonia immunization under subsection (b)(3), are at least fifty (50) years of age.
(5) Before administering an immunization to an individual

according to a protocol approved by a physician, the pharmacist must receive the consent of one (1) of the following:

(A) If the individual to whom the immunization is to be administered is at least eleven (11) years of age but less than eighteen (18) years of age, the parent or legal guardian of the individual.

(B) If the individual to whom the immunization is to be administered is at least eighteen (18) years of age but has a legal guardian, the legal guardian of the individual.

(C) If the individual to whom the immunization is to be administered is at least eighteen (18) years of age but has no legal guardian, the individual.

A parent or legal guardian who is required to give consent under this subdivision must be present at the time of immunization.

(d) If the state department of health or the department of homeland security determines that an emergency exists, subject to IC 16-41-9-1.7(a)(2), a pharmacist may administer any immunization in accordance with:

(1) the requirements of subsection (c)(1) through (c)(3); and

(2) any instructions in the emergency determination.

(e) A pharmacist or pharmacist's designee shall provide immunization data to the immunization data registry (IC 16-38-5) in a manner prescribed by the state department of health unless:

(1) the individual receiving the immunization;

(2) the parent of the individual receiving the immunization, if the individual receiving the immunization is less than eighteen (18) years of age; or

(3) the legal guardian of the individual receiving the immunization, if a legal guardian has been appointed;

has completed and filed with the pharmacist or pharmacist's designee a written immunization data exemption form, as provided in IC 16-38-5-2.

(f) If an immunization is administered under a protocol, then the name, license number, and contact information of the physician who wrote the protocol must be posted in the location where the immunization is administered. A copy of the protocol must be available for inspection by the individual receiving the immunization.

(g) A pharmacist may administer an immunization that is provided according to a standing order, prescription, or protocol issued under this section or IC 16-19-4-11 by the state health commissioner or the commissioner's designated public health authority who is a licensed prescriber. If a pharmacist has received a protocol to administer an

immunization from a physician and that specific immunization is covered by a standing order, prescription, or protocol issued by the state health commissioner or the commissioner's designated public health authority, the pharmacist must administer the immunization according to the standing order, prescription, or protocol issued by the state health commissioner or the commissioner's designated public health authority.

SECTION 17. IC 25-26-13-31.5, AS AMENDED BY P.L.129-2018, SECTION 38, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 31.5. (a) Subject to rules adopted under subsection (c), a pharmacist intern or a pharmacist student may administer an immunization to an individual under a drug order or prescription.

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

(c) The board shall adopt rules under IC 4-22-2 to establish requirements applying to a pharmacist intern or a pharmacist student who administers an immunization to an individual or group of individuals. The rules adopted under this section:

(1) must provide for the direct supervision of the pharmacist intern or pharmacist student by a pharmacist, a physician, a physician assistant, ~~or~~ an advanced practice registered nurse, **or a registered nurse;** and

(2) may not be less stringent than the requirements applying to a pharmacist who administers an immunization to an individual as provided under section 31.2 of this chapter.

SECTION 18. IC 25-26-13-31.7, AS ADDED BY P.L.114-2020, SECTION 14, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 31.7. (a) Subject to rules adopted under subsection (c), a pharmacy technician may administer an influenza **or coronavirus disease** immunization to an individual under a drug order or prescription.

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

(c) The board shall adopt rules under IC 4-22-2 to establish requirements applying to a pharmacy technician who administers an influenza **or coronavirus disease** immunization to an individual or

group of individuals. The rules adopted under this section must provide for the direct supervision of the pharmacy technician by a pharmacist, a physician, a physician assistant, or an advanced practice registered nurse. **Before July 1, 2021, the board shall adopt emergency rules under IC 4-22-2-37.1 to establish the requirements described in this subsection concerning the influenza immunization and the coronavirus disease immunization.**

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

SECTION 19. IC 25-26-13.5-6, AS ADDED BY P.L.202-2017, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 6. (a) Before a remote dispensing facility may do business in Indiana, the remote dispensing facility must be registered with the board under this chapter and in the manner prescribed by the board.

(b) Before a pharmacy licensed under this article may operate a remote dispensing facility, the pharmacy must register with the board under this chapter.

(c) A facility must meet the following requirements in order to be registered as a remote dispensing facility under this chapter:

(1) If the remote dispensing facility is not jointly owned by the pharmacy, operate under a contract with a supervising pharmacy.

(2) Be supervised by a qualifying pharmacist who is licensed under this article and who is designated by the supervising pharmacy to be responsible for oversight of the remote dispensing facility.

(3) Be located at least ten (10) miles from an existing retail pharmacy unless:

(A) the applicant with the proposed remote dispensing facility demonstrates to the board how the proposed remote dispensing facility will promote public health; or

(B) the ~~pharmacy located less than ten (10) miles from the~~ remote dispensing facility ~~is part of a hospital or a physician clinic setting.~~ **exclusively serves the patients of:**

(i) a community mental health center established under IC 12-29;

(ii) a health care facility (as defined in IC 16-28-13-0.5); or

(iii) a physician clinic.

(4) Maintain a patient counseling area.

(5) Display a sign visible to the public indicating that the location

is a remote dispensing facility. The sign must include the following information:

(A) That the facility provides remote services supervised by a pharmacist located in another pharmacy.

(B) The identification and address of the supervising pharmacy.

(C) Disclosure that a pharmacist is required to speak to the consumer using audio and video communication systems any time a new drug or device is dispensed at the remote dispensing facility.

(D) Whether patient counseling is provided on a prescription drug refill at the remote dispensing facility.

(E) That the facility is under continuous video surveillance and that the video is recorded.

(d) If the remote dispensing facility is operating under a contract with a supervising pharmacy, the contract must:

(1) specify the responsibilities of each party to the contract; and

(2) be available for review by the board at the board's request.

SECTION 20. IC 25-26-13.5-11, AS AMENDED BY P.L.246-2019, SECTION 17, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 11. (a) A supervising pharmacy of a remote dispensing facility must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy, the remote dispensing facility, and any consumers. The system must do the following:

(1) Provide an adequate number of views of the entire remote dispensing facility.

(2) Facilitate adequate pharmacist supervision.

(3) Allow an appropriate exchange of visual, verbal, and written communications for patient counseling and other matters concerning the lawful transaction of business.

(b) The remote dispensing facility must retain a recording of facility surveillance, excluding patient communications, for at least ~~forty-five (45)~~ **thirty (30)** days.

(c) A qualifying pharmacist is adequately supervising through the use of video surveillance by maintaining constant visual supervision and auditory communication with the remote dispensing facility and by maintaining full supervisory control of the automated system, if applicable. The auditory communication must be available, as needed, with the remote dispensing facility and the qualifying pharmacist.

(d) A video monitor that is being used to properly identify and communicate with consumers must meet the following requirements:

~~(1) Be at least twelve (12) inches wide.~~

~~(2) Be high definition.~~

~~(3)~~ **(1)** Provide both the supervising pharmacy and the remote dispensing facility with direct visual contact between the pharmacist and the consumer.

~~(4)~~ **(2)** Be secure and compliant with the federal Health Insurance Portability and Accountability Act (HIPAA).

(e) If any component of the communication system is not in operating order, the remote dispensing facility shall remain closed until the communication system is fully operational, unless a pharmacist is located at the remote dispensing facility.

SECTION 21. IC 25-26-16-1, AS AMENDED BY P.L.202-2017, SECTION 13, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 1. As used in this chapter, "protocol" means the policies, procedures, and protocols of a:

(1) hospital listed in IC 16-18-2-161(a)(1);

(2) physician licensed under IC 25-22.5; or

(3) physician group practice;

concerning the adjustment of a patient's drug regimen by, **or other patient care services delegated to,** a pharmacist **licensed under this article.**

SECTION 22. IC 25-26-16-1.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: **Sec. 1.5. As used in this chapter, "therapeutic alternative" means a drug product that:**

(1) has a different chemical structure from;

(2) is in the same pharmacological or therapeutic class as; and

(3) usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses as;

another drug.

SECTION 23. IC 25-26-16-2, AS AMENDED BY P.L.202-2017, SECTION 14, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 2. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist:

(1) changes the duration of treatment for a current drug therapy;

(2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration;

(3) discontinues the use of a drug;

(4) adds a drug to the treatment regimen; ~~or~~

(5) issues a new prescription for the purposes of subdivision (1), (2), or (4); **or**

(6) makes a therapeutic substitution.

SECTION 24. IC 25-26-16-4.5, AS AMENDED BY P.L.129-2018, SECTION 39, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 4.5. (a) This section does not apply to a pharmacist who is practicing in a hospital.

(b) As used in this section, "direct supervision" means that a supervising:

(1) physician;

(2) advanced practice registered nurse who meets the requirements of IC 25-23-1-19.5; or

(3) physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6;

is readily available to consult with the pharmacist while the protocol services are being provided.

(c) This section applies to a pharmacist who:

(1) is employed by, or has entered into a contract with, a physician, a group of physicians, or an outpatient clinic; and

(2) is under the direct supervision of a person described in subsection (b)(1) through (b)(3).

(d) The protocols developed under this chapter:

(1) must be agreed upon by:

(A) the physician or the physician administrator described in section 3.5(d) of this chapter; and

(B) the pharmacist; **and**

~~(2) must, at a minimum, require that:~~

~~(A) the medical records of the patient are available to both the patient's physician and the pharmacist; and~~

~~(B) the procedures performed by the pharmacist relate to a condition for which the patient has first seen the physician or another licensed practitioner; and~~

~~(3)~~ **(2)** may apply to a single patient or group of patients, as specified by the physician.

SECTION 25. IC 25-26-16-10 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: **Sec. 10. If a protocol developed under this chapter allows a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician, the attending physician's authorization of the substitution is valid only for the duration of the prescription or drug order.**

SECTION 26. IC 25-26-16-11 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS

[EFFECTIVE JULY 1, 2021]: **Sec. 11. A pharmacist may not substitute a therapeutic alternative for a drug prescribed by an individual's attending physician unless the substitution is authorized by the attending physician under a valid protocol issued under this chapter.**

SECTION 27. IC 25-26-16-12 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: **Sec. 12. A physician assistant licensed under IC 25-27.5 or an advanced practice registered nurse licensed under IC 25-23 may refer a patient to a pharmacist under a protocol.**

SECTION 28. IC 25-26-16.5-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 3. As used in this chapter, "protocol" means a policy, procedure, or protocol of a health facility concerning:

(1) the adjustment of a patient's drug regimen as allowed under this chapter by; **or**

(2) other patient care services delegated to;

a pharmacist licensed under this article.

SECTION 29. IC 25-26-16.5-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 5. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist:

(1) changes the duration of treatment for a current drug therapy;

(2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration;

(3) discontinues the use of a drug; ~~or~~

(4) adds a drug to the treatment regimen;

(5) issues a new prescription for the purposes of subdivisions (1), (2), or (4); or

(6) makes a therapeutic substitution.

SECTION 30. IC 27-1-24.5-5, AS ADDED BY P.L.68-2020, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 5. As used in this chapter, "health plan" means the following:

(1) A state employee health plan (as defined in IC 5-10-8-6.7).

(2) A policy of accident and sickness insurance (as defined in IC 27-8-5-1). However, the term does not include the coverages described in IC 27-8-5-2.5(a).

(3) An individual contract (as defined in IC 27-13-1-21) or a group contract (as defined in IC 27-13-1-16) that provides coverage for basic health care services (as defined in IC 27-13-1-4).

(4) Any other plan or program that provides payment, reimbursement, or indemnification to a covered individual for the cost of prescription drugs.

SECTION 31. **An emergency is declared for this act.**

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1468, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 2, line 41, delete "shall" and insert "**may**".

Page 6, delete lines 14 through 42.

Page 7, delete lines 1 through 29.

Page 9, delete lines 32 through 42.

Delete pages 10 through 13.

Page 14, delete line 1.

Page 19, between lines 12 and 13, begin a new paragraph and insert:

"SECTION 26. IC 27-1-24.5-5, AS ADDED BY P.L.68-2020, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2021]: Sec. 5. As used in this chapter, "health plan" means the following:

(1) A state employee health plan (as defined in IC 5-10-8-6.7).

(2) A policy of accident and sickness insurance (as defined in IC 27-8-5-1). However, the term does not include the coverages described in IC 27-8-5-2.5(a).

(3) An individual contract (as defined in IC 27-13-1-21) or a group contract (as defined in IC 27-13-1-16) that provides coverage for basic health care services (as defined in IC 27-13-1-4).

(4) Any other plan or program that provides payment, reimbursement, or indemnification to a covered individual for the cost of prescription drugs.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1468 as introduced.)

BARRETT

Committee Vote: yeas 12, nays 0.

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1468, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 5, line 20, after "failure;" strike "or".

Page 5, line 23, delete "." and insert "; **or**

(C) the inability of the dispensing pharmacy or provider to receive or process an electronically transmitted prescription.".

Page 6, between lines 13 and 14, begin a new paragraph and insert:

"SECTION 9. IC 25-1-9.3-9, AS AMENDED BY P.L.114-2020, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 9. (a) The board shall, in consultation with the medical licensing board, adopt rules under IC 4-22-2 to implement this chapter, including:

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

(A) economic hardship;

(B) technological limitations outside the control of the prescriber **that are not otherwise specified in section 8 of this chapter;** or

(C) other circumstances determined by the board; and

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

(b) Any rules adopted under this chapter must be substantially similar to the requirements and exceptions under:

(1) 42 U.S.C. 1395w-104; **and**

(2) any regulations adopted under 42 U.S.C. 1395w-104.

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

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

(2) July 1, 2023.

(d) A provision described in:

(1) section 8(1) through 8(4);

(2) section 8(6); and

(3) section 8(7);

of this chapter does not require a waiver of any rule adopted under this chapter.

SECTION 10. IC 25-26-13-2, AS AMENDED BY P.L.89-2015, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 2. As used in this chapter:

"Administering" means the direct application of a drug to the body of a person by injection, inhalation, ingestion, or any other means.

"Board" means the Indiana board of pharmacy.

"Controlled drugs" are those drugs on schedules I through V of the federal Controlled Substances Act or on schedules I through V of IC 35-48-2.

"Coronavirus disease" means the disease caused by the severe acute respiratory syndrome coronavirus 2 virus (SARS-CoV-2).

"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

"Dispensing" means issuing one (1) or more doses of a drug in a suitable container with appropriate labeling for subsequent administration to or use by a patient.

"Drug" means:

(1) articles or substances recognized in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them;

(2) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) articles other than food intended to affect the structure or any function of the body of man or animals; or

(4) articles intended for use as a component of any article specified in subdivisions (1) through (3) and devices.

"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in

quantity or days; adequate directions for the proper use of the drug or device when it is administered to the patient; and the name of the prescriber.

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, which is:

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Electronic data intermediary" means an entity that provides the infrastructure that connects a computer system or another electronic device used by a prescribing practitioner with a computer system or another electronic device used by a pharmacy to facilitate the secure transmission of:

(1) an electronic prescription order;

(2) a refill authorization request;

(3) a communication; and

(4) other patient care information;

between a practitioner and a pharmacy.

"Electronic signature" means an electronic sound, symbol, or process:

(1) attached to or logically associated with a record; and

(2) executed or adopted by a person;

with the intent to sign the record.

"Electronically transmitted" or "electronic transmission" means the transmission of a prescription in electronic form. The term does not include the transmission of a prescription by facsimile.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Medication therapy management" means a distinct service or group of services that optimize therapeutic outcomes for individuals that are independent of, but may occur in conjunction with, the provision of a medication or medical device. The term includes the following services:

(1) Performing or obtaining assessments of an individual's health status.

(2) Formulating a medication treatment plan.

(3) Selecting, initiating, modifying, or administering medication therapy.

(4) Monitoring and evaluating an individual's response to therapy, including safety and effectiveness.

(5) Performing a comprehensive medication review to identify, resolve, and prevent medication related problems, including adverse drug events.

(6) Documenting the care delivered and communicating essential information to the patient's other health care providers.

(7) Providing education and training designed to enhance patient understanding and appropriate use of the individual's medications.

(8) Providing information and support services and resources designed to enhance patient adherence with the individual's therapeutic regimens, including medication synchronization.

(9) Coordinating and integrating medication therapy management services within the broader health care services being provided to an individual.

(10) Providing other patient care services allowable by law.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" has the meaning set forth in IC 16-42-19-5.

"Pharmacist" means a person licensed under this chapter.

"Pharmacist intern" means a person who is:

(1) permitted by the board to engage in the practice of pharmacy while under the personal supervision of a pharmacist and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) a graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate and who is permitted by the board to obtain practical experience as a requirement for licensure as a pharmacist;

(3) a qualified applicant awaiting examination for licensure; or

(4) an individual participating in a residency or fellowship program.

"Pharmacy" means any facility, department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern or an unlicensed person under section 18.5 of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug

order or sold or given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist under this article.

(8) Provision of medication therapy management.

"Prescription" means a written order or an order transmitted by other means of communication from a practitioner to or for an ultimate user for any drug or device containing:

(1) the name and address of the patient;

(2) the date of issue;

(3) the name and strength or size (if applicable) of the drug or device;

(4) the amount to be dispensed (unless indicated by directions and duration of therapy);

(5) adequate directions for the proper use of the drug or device by the patient;

(6) the name of the practitioner; and

(7) if the prescription:

(A) is in written form, the signature of the practitioner; or

(B) is in electronic form, the electronic signature of the practitioner.

"Qualifying pharmacist" means the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operations of the pharmacy under the permit.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents, or objects which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.".

Page 9, between lines 6 and 7, begin a new paragraph and insert:

"SECTION 15. IC 25-26-13-31.2, AS AMENDED BY P.L.202-2017, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 31.2. (a) A pharmacist may administer an immunization to an individual under a drug order or prescription.

(b) Subject to subsection (c), a pharmacist may administer immunizations for the following to a group of individuals under a drug order, under a prescription, or according to a protocol approved by a physician:

(1) Influenza.

(2) Shingles (herpes zoster).

(3) Pneumonia.

(4) Tetanus, diphtheria, and acellular pertussis (whooping cough).

(5) Human papillomavirus (HPV) infection.

(6) Meningitis.

(7) Measles, mumps, and rubella.

(8) Varicella.

(9) Hepatitis A.

(10) Hepatitis B.

(11) Haemophilus influenzae type b (Hib).

(12) Coronavirus disease.

(c) A pharmacist may administer an immunization under subsection (b) if the following requirements are met:

(1) The physician specifies in the drug order, prescription, or protocol the group of individuals to whom the immunization may be administered.

(2) The physician who writes the drug order, prescription, or protocol is licensed and actively practicing with a medical office in Indiana and not employed by a pharmacy.

(3) The pharmacist who administers the immunization is responsible for notifying, not later than fourteen (14) days after the pharmacist administers the immunization, the physician who authorized the immunization and the individual's primary care physician that the individual received the immunization.

(4) If the physician uses a protocol, the protocol may apply only

to an individual or group of individuals who:

(A) except as provided in clause (B), are at least eleven (11) years of age; or

(B) for the pneumonia immunization under subsection (b)(3), are at least fifty (50) years of age.

(5) Before administering an immunization to an individual according to a protocol approved by a physician, the pharmacist must receive the consent of one (1) of the following:

(A) If the individual to whom the immunization is to be administered is at least eleven (11) years of age but less than eighteen (18) years of age, the parent or legal guardian of the individual.

(B) If the individual to whom the immunization is to be administered is at least eighteen (18) years of age but has a legal guardian, the legal guardian of the individual.

(C) If the individual to whom the immunization is to be administered is at least eighteen (18) years of age but has no legal guardian, the individual.

A parent or legal guardian who is required to give consent under this subdivision must be present at the time of immunization.

(d) If the state department of health or the department of homeland security determines that an emergency exists, subject to IC 16-41-9-1.7(a)(2), a pharmacist may administer any immunization in accordance with:

(1) the requirements of subsection (c)(1) through (c)(3); and

(2) any instructions in the emergency determination.

(e) A pharmacist or pharmacist's designee shall provide immunization data to the immunization data registry (IC 16-38-5) in a manner prescribed by the state department of health unless:

(1) the individual receiving the immunization;

(2) the parent of the individual receiving the immunization, if the individual receiving the immunization is less than eighteen (18) years of age; or

(3) the legal guardian of the individual receiving the immunization, if a legal guardian has been appointed;

has completed and filed with the pharmacist or pharmacist's designee a written immunization data exemption form, as provided in IC 16-38-5-2.

(f) If an immunization is administered under a protocol, then the name, license number, and contact information of the physician who wrote the protocol must be posted in the location where the immunization is administered. A copy of the protocol must be available

for inspection by the individual receiving the immunization.

(g) A pharmacist may administer an immunization that is provided according to a standing order, prescription, or protocol issued under this section or IC 16-19-4-11 by the state health commissioner or the commissioner's designated public health authority who is a licensed prescriber. If a pharmacist has received a protocol to administer an immunization from a physician and that specific immunization is covered by a standing order, prescription, or protocol issued by the state health commissioner or the commissioner's designated public health authority, the pharmacist must administer the immunization according to the standing order, prescription, or protocol issued by the state health commissioner or the commissioner's designated public health authority.

SECTION 16. IC 25-26-13-31.5, AS AMENDED BY P.L.129-2018, SECTION 38, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 31.5. (a) Subject to rules adopted under subsection (c), a pharmacist intern or a pharmacist student may administer an immunization to an individual under a drug order or prescription.

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

(c) The board shall adopt rules under IC 4-22-2 to establish requirements applying to a pharmacist intern or a pharmacist student who administers an immunization to an individual or group of individuals. The rules adopted under this section:

(1) must provide for the direct supervision of the pharmacist intern or pharmacist student by a pharmacist, a physician, a physician assistant, ~~or~~ an advanced practice registered nurse, **or a registered nurse;** and

(2) may not be less stringent than the requirements applying to a pharmacist who administers an immunization to an individual as provided under section 31.2 of this chapter.

SECTION 17. IC 25-26-13-31.7, AS ADDED BY P.L.114-2020, SECTION 14, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 31.7. (a) Subject to rules adopted under subsection (c), a pharmacy technician may administer an influenza **or coronavirus disease** immunization to an individual under a drug order or prescription.

(b) Subject to rules adopted under subsection (c), a pharmacy technician may administer an influenza **or coronavirus disease**

immunization to an individual or a group of individuals under a drug order, under a prescription, or according to a protocol approved by a physician.

(c) The board shall adopt rules under IC 4-22-2 to establish requirements applying to a pharmacy technician who administers an influenza **or coronavirus disease** immunization to an individual or group of individuals. The rules adopted under this section must provide for the direct supervision of the pharmacy technician by a pharmacist, a physician, a physician assistant, or an advanced practice registered nurse. **Before July 1, 2021, the board shall adopt emergency rules under IC 4-22-2-37.1 to establish the requirements described in this subsection concerning the influenza immunization and the coronavirus disease immunization.**

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

Page 9, line 30, strike "is".

Page 9, line 31, delete "located within the same building as, and".

Page 9, line 32, delete "serves," and insert "**serves**".

Page 13, line 7, delete "." and insert "**under a protocol.**".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1468 as printed February 15, 2021.)

CHARBONNEAU, Chairperson

Committee Vote: Yeas 11, Nays 0.