HOUSE ENROLLED ACT No. 1246

AN ACT to amend the Indiana Code concerning health.

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

SECTION 1. IC 12-12.7-2-22 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 22. Notwithstanding any other law, any appropriation made to a program established under this chapter and 20 U.S.C. 1431 through 1444 (first steps program) that exceeds eleven million three hundred thirty-nine thousand sixty-three dollars ($11,339,063) in a state fiscal year must be distributed by the office of the secretary of family and social services as follows:

1. Not more than ten percent (10%) to the division of disability and rehabilitative services for infrastructure expenses.
2. Not less than forty percent (40%) to systems point of entry contracts.
3. Not less than fifty percent (50%) to rates of providers who provide services under this chapter and 20 U.S.C. 1431 through 1444.

SECTION 2. IC 12-15-1.3-21 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 21. (a) As used in this section, "Medicaid rehabilitation option services" means clinical behavioral health services provided to recipients and families of recipients living in the community who need aid intermittently for
emotional disturbances, mental illness, and addiction as part of the Medicaid rehabilitation option program.

(b) Before December 1, 2019, the office may apply to the United States Department of Health and Human Services for a state plan amendment that would require Medicaid reimbursement by:

1. the office;
2. a managed care organization that has contracted with the office; or
3. a contractor of the office;

for eligible Medicaid rehabilitation option services in a school setting for any Medicaid recipient who qualifies for Medicaid rehabilitation option services by meeting specific diagnosis and level of need criteria under an assessment tool approved by the division of mental health and addiction or who submits prior authorization for Medicaid rehabilitation option services.

(c) If the office receives approval for the state plan amendment applied for under this section, the office shall comply with IC 12-15-5-19.

SECTION 3. IC 12-15-5-19 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 19. (a) Not later than one (1) year from the date the office receives approval for the state plan amendment described in IC 12-15-1.3-21 concerning Medicaid rehabilitation option services, the office shall do the following:

1. Review the current services included in the Medicaid rehabilitation option services program in the school setting.
2. Determine whether additional appropriate services, including:
   (A) family engagement services; and
   (B) additional comprehensive behavioral health services, including addiction services;
should be included as part of the program.
3. Report the office's findings under this subsection to the general assembly in an electronic format under IC 5-14-6.

(b) Not later than three (3) months from the date the office receives approval for the state plan amendment described in IC 12-15-1.3-21 concerning Medicaid rehabilitation option services, the office shall notify each school corporation that the United States Department of Health and Human Services has approved the state plan amendment applied for under IC 12-15-1.3-21.

(c) Each school corporation shall, not later than one (1) year
from the date the office receives approval for the state plan amendment described in IC 12-15-1.3-21 concerning Medicaid rehabilitation option services, contract with a community mental health center to provide Medicaid rehabilitation option services for:

(1) a student of the school corporation who is a Medicaid recipient; and
(2) the student's family.

SECTION 4. IC 12-23-23-1, AS ADDED BY P.L.195-2018, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 1. As used in this chapter, "employee" means an individual who:

(1) has recently been hired by an employer; or
(2) is a current employee;

and failed a drug screening. and is not covered by an employment assistance program.

SECTION 5. IC 12-23-23-12, AS ADDED BY P.L.195-2018, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 12. (a) If an employer complies with the requirements under this chapter, the employer is not liable for a civil action alleging negligent hiring for a negligent action by the employee as a result of the employee's drug addiction in the scope of employment.

(b) Referral and treatment by an employee assistance program is not sufficient to constitute compliance with this chapter unless all the other requirements of this chapter are met.

(b) (c) In a civil action that is against an employer, an employer's agent, or an employer's employee, an employer's participation in a drug education or addiction treatment program is not admissible as evidence.

SECTION 6. IC 16-21-1-7, AS AMENDED BY SEA 575-2019, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 7. (a) The executive board may adopt rules under IC 4-22-2 necessary to protect the health, safety, rights, and welfare of patients, including the following:

(1) Rules pertaining to the operation and management of hospitals, ambulatory outpatient surgical centers, abortion clinics, and birthing centers.

(2) Rules establishing standards for equipment, facilities, and staffing required for efficient and quality care of patients.

(b) Notwithstanding 410 IAC 15-1.7-1 and 410 IAC 15-2.7-1, the following apply to a publication that is referred to in 410 IAC 15:
The Guidelines for Construction and Equipment of Hospital and Medical Facilities refers to the following:
(A) The 2018 edition or most recent publication of the Guidelines for Design and Construction of Hospitals.
(B) The 2018 edition or most recent publication of the Guidelines for Design and Construction of Outpatient Facilities.

The National Fire Protection Association (NFPA) 101, Life Safety Code Handbook publication refers to the 2018 edition or most recent publication.

The National Fire Protection Association 99, Health Care Facilities publication refers to the 2018 edition or most recent publication.

A publication incorporated by reference is not effective until one hundred eighty (180) days after the date of publication. The executive board shall amend 410 IAC 15-1.7-1 and 410 IAC 15-2.7-1 to reflect the requirements in this subsection. This subsection expires July 1, 2021.

SEC 7. IC 16-27-2.5-2, AS ADDED BY P.L.224-2017, SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 2. (a) A home health agency must:
(1) have a written drug testing policy that is distributed to all employees; and
(2) require each employee to acknowledge receipt of the policy.

(b) A home health agency shall randomly test:
(1) at least fifty percent (50%) of the home health agency's employees who:
   (A) have direct contact with patients; and
   (B) are not licensed by a board or commission under IC 25; at least annually; or
   and
(2) when the home health agency has reasonable suspicion that an employee is engaged in the illegal use of a controlled substance.
(c) A home health agency shall either discharge or discipline with a minimum of a six (6) month suspension an employee who refuses to submit to a drug test.

SEC 8. IC 25-26-13-17, AS AMENDED BY P.L.202-2017, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 17. (a) The board shall establish classes of pharmacy permits as follows:

Category I. A retail permit for a pharmacy that provides pharmaceutical care to the general public by the dispensing of a drug or device.

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Category II. An institutional permit for hospitals, clinics, health care facilities, sanitariums, nursing homes, or dispensaries that offer pharmaceutical care by dispensing a drug product to an inpatient under a drug order or to an outpatient of the institution under a prescription.

Category III. A permit for a pharmacy that provides closed door, central fill, mail order, or other processing operations that are not open to the general public but include:

(A) traditional pharmacy functions; or
(B) nontraditional pharmacy functions, such as infusion, nuclear pharmacy, or sterile compounding.

(b) Except for when registration as a remote dispensing facility (as defined in IC 25-26-13.5-3) is required under IC 25-26-13.5, the board may approve a remote or mobile location for Category I, II, or III permits and any nonresident pharmacy registered with the board. Pharmacy practice in a mobile or remote location may include, but is not limited to, telepharmacy, automated dispensing, or delivery of cognitive services.

(c) A hospital or hospital system holding a Category II permit may offer drugs or devices:

(1) to:
   (A) an employee, student, or volunteer of the hospital or hospital system;
   (B) a retiree who is participating in a retirement, pension, or benefit program administered by the hospital or hospital system;
   (C) an independent contractor who has an exclusive relationship with the hospital or hospital system;
   (D) a member of the hospital's or hospital system's governing board; or
   (E) a member of the hospital's or hospital system's medical staff; and

(2) to dependents of the individuals listed in subdivision (1); for their own use.

(d) Hospitals holding a Category II permit may operate remote locations within a reasonable distance of the licensed area, as determined by the board, after:

(1) filing an application on a form prepared by the board;
(2) having each location inspected by the board; and
(3) obtaining approval from the board.

(e) Any applicable rule governing the practice of pharmacy in Indiana shall apply to all permits under this section.
(f) After June 30, 2012, a person with:
(1) a Type I permit shall be treated as holding a Category I permit;
(2) a Type II permit shall be treated as holding a Category II permit; and
(3) a Type III, IV, V, or VI permit shall be treated as holding a Category III permit.
The change in the name of the permit does not change the expiration date of the permit.

(g) After June 30, 2012, a reference in any rule or other document to:
(1) a Type I permit shall be treated as a reference to a Category I permit;
(2) a Type II permit shall be treated as a reference to a Category II permit; or
(3) a Type III, IV, V, or VI permit shall be treated as a reference to a Category III permit.

(h) A pharmacy holding a Category I permit may offer drugs or devices to the following:
(1) A long term care facility licensed under or subject to IC 16-28-2.
(2) A health facility licensed under IC 16-28.
(3) A housing with services establishment (as defined in IC 12-10-15-3) registered with the office of the secretary of family and social services.

SECTION 9. IC 25-26-13-24.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]:
Sec. 24.8. Upon request of a patient, a pharmacy shall transfer to another pharmacy a prescription for the patient that the pharmacy has received but not filled unless:
(1) prohibited in writing on the prescription by the prescriber; or
(2) otherwise prohibited by federal law.

SECTION 10. IC 25-26-13-25.3 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]:
Sec. 25.3. Beginning January 1, 2020, a pharmacy may not dispense injectable epinephrine or glucagon to a person unless:
(1) the injectable epinephrine or glucagon has an expiration date of not less than twelve (12) months from the date that the drug is dispensed; or
(2) the person consents to the injectable epinephrine or glucagon having an expiration date of less than twelve (12)
months from the date that the drug is dispensed.

SECTION 11. IC 25-26-13.5-1.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 1.5. (a) As used in this chapter, "automated dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for the drugs.

(b) The term does not include an automated dispensing system that is located in a hospital licensed under IC 16-21-2, an ambulatory outpatient surgical center licensed under IC 16-21-2, a health facility licensed under IC 16-28, or a pharmacy licensed under IC 25-26-13.

SECTION 12. IC 25-26-13.5-3, AS ADDED BY P.L.202-2017, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 3. As used in this chapter, "remote dispensing facility" means a facility or an automated dispensing system where prescription drugs are prepared or dispensed without the requirement of the use of an onsite pharmacist and where pharmacist supervision may be provided remotely. However, the term does not include a facility or an automated dispensing system that is located in a hospital licensed under IC 16-21-2, an ambulatory outpatient surgical center licensed under IC 16-21-2, or a health facility licensed under IC 16-28, or an automated dispensing system.

SECTION 13. IC 25-26-13.5-6.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 6.5. (a) The registration required under this chapter is in addition to any other registration or permit required under this article.

(b) The board shall establish a registration procedure for automated dispensing systems. An application for registration of an automated dispensing system must include the following information:

(1) A description of the automated dispensing system being used at the facility, including information concerning any of the following:

(A) Telepharmacy communication.
(B) Electronic record keeping.
(C) Electronic verification systems.

(2) Operating specifications of the automated dispensing
system, including the following:

(A) Location of the facility using the automated dispensing system.

(B) Ownership of the automated dispensing system.

(C) Identification of personnel responsible for operation of the automated dispensing system.

(3) A scale drawing that illustrates the layout and location of the automated dispensing system.

(4) Identification of the proposed supervising pharmacy.

(c) A supervising pharmacy of an automated dispensing system must be located in Indiana and licensed under this article.

SECTION 14. IC 25-26-13.5-6.7 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS follows [EFFECTIVE JULY 1, 2019]: Sec. 6.7. (a) Before a pharmacy may operate an automated dispensing system, the automated dispensing system must be registered with the board under this chapter and in the manner prescribed by the board.

(b) The board shall establish minimum standards and practices that ensure the safety, accuracy, security, record keeping, and patient confidentiality of an automated dispensing system.

SECTION 15. IC 25-26-13.5-8, AS ADDED BY P.L.202-2017, SECTION 12, IS AMENDED TO READ AS follows [EFFECTIVE JULY 1, 2019]: Sec. 8. (a) The qualifying pharmacist and a pharmacist on duty are responsible for ensuring that the supervising pharmacy and remote dispensing facility are sufficiently staffed to avoid the risk of harm to public health and safety.

(b) In order to serve as a qualifying pharmacist, the pharmacist must be in good standing with the board.

(c) A qualifying pharmacist may have this designation for only one (1) supervising pharmacy and for one (1) remote dispensing facility at a time.

(d) A qualifying pharmacist must be able to be physically at the remote dispensing facility within a certain time set by the board to address emergencies and safety issues that arise. However, in the qualifying pharmacist's absence the qualifying pharmacist may designate another pharmacist to fulfill the qualifying pharmacist's duties at the remote dispensing facility.

(e) A qualifying pharmacist shall visit a remote dispensing facility at least as often as required by the board to inspect the facility and address personnel matters. The qualifying pharmacist shall complete any forms required by the board concerning the required inspection and maintain the records in a manner specified by the board.
(f) If the remote dispensing facility is located at a hospital or physician clinic and uses an automated dispensing machine, the qualifying pharmacist shall maintain an up to date inventory of any schedule II controlled substances. The qualifying pharmacist shall at least monthly inventory all controlled substances.

(g) The qualifying pharmacist shall develop and implement a continuous quality improvement program. The program must include a reporting mechanism for errors that occur concerning the remote dispensing facility. Information concerning the program must be available to the board upon request.

SECTION 16. IC 25-26-13.5-9, AS ADDED BY P.L.202-2017, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 9. (a) There must be at least one (1) pharmacist working at a remote dispensing facility for every six (6) pharmacist interns, licensed pharmacy technicians, and pharmacy technicians in training at the supervising pharmacy and remote dispensing facility. However, an individual whose only duty is to act as the cashier is not included in the number of employees that may work for one (1) pharmacist under this subsection.

(b) A remote dispensing facility that is not staffed by a pharmacist must be staffed by at least one (1) pharmacy technician who meets the following requirements:

1. Is licensed under IC 25-26-19.
2. Has at least two thousand (2,000) hours of experience working as a pharmacy technician in a pharmacy licensed under this article and under the direct supervision of a pharmacist.
3. Has successfully passed a certification examination offered by the Pharmacy Technician Certification Board or another nationally recognized certification body approved by the board.
4. If the remote dispensing facility is located in a hospital or physician clinic setting, either:
   1. Has graduated from a pharmacy technician training program accredited by the American Council of Pharmaceutical Education or the American Society of Health System Pharmacists; or
   2. Obtained the hours described in subdivision (2) before July 1, 2017.
5. Is supervised by a pharmacist at the supervising pharmacy at all times that the remote dispensing facility is operational. As used in this subdivision, supervision does not require that the pharmacist be physically present at the remote dispensing facility as long as the pharmacist is supervising telepharmacy operations.
electronically through a computer link, video link, and audio link.

(6) Is currently in good standing with the board.

(c) A pharmacy technician in training may not work at a remote dispensing facility unless a pharmacist is on site.

(d) **The board shall adopt rules that require pharmacy technicians working at a remote dispensing facility that is not staffed by a pharmacist to complete continuing education requirements established by the board.**

SECTION 17. IC 25-26-13.5-11, AS ADDED BY P.L.202-2017, SECTION 12, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: 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) 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. Provide both the supervising pharmacy and the remote dispensing facility with direct visual contact between the pharmacist and the consumer.
4. 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 18. IC 25-26-13.5-18, AS AMENDED BY P.L.209-2018, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JUNE 1, 2019]: Sec. 18. (a) The board may adopt rules under IC 4-22-2 necessary to implement this chapter.

(b) The Indiana board of pharmacy shall not later than July 1, 2018, adopt rules under IC 4-22-2, including emergency rules in the manner provided under IC 4-22-2-37.1, to implement sections 6.5 and 6.7 of this chapter with respect to telepharmacy. This subsection expires July 1, 2019; 2020.

SECTION 19. IC 25-26-14-11, AS AMENDED BY P.L.212-2005, SECTION 45, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 11. As used in this chapter, "wholesale distribution" means to distribute legend drugs to persons other than a consumer or patient. The term does not include:

1. a sale or transfer between a division, a subsidiary, a parent, an affiliated, or a related company under the common ownership and control of a corporate entity;
2. the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of the organization;
3. the sale or transfer of a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, to:
   A) a nonprofit affiliate of the organization; or
   B) a nonprofit entity described in Section 501(c)(3) of the Internal Revenue Code that is not affiliated with the organization; to the extent otherwise permitted by law;
4. the sale of a drug among hospitals or other health care entities that are under common control;
5. the sale of a drug for emergency medical reasons, including transfers of legend drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfers does not exceed five percent (5%) of the total legend drug sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period;
6. the sale of a drug or the dispensing of a drug pursuant to a prescription;
(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives;
(8) the sale of blood and blood components intended for transfusion;
(9) the sale of a drug by a retail pharmacy to a practitioner (as defined in IC 25-26-13-2) for office use, if the gross dollar value of the transfers does not exceed five percent (5%) of the retail pharmacy's total legend drug sales during any twelve (12) consecutive months;
(10) the sale of a drug by a retail pharmacy that is ending its business and liquidating its inventory to another retail pharmacy;
(11) drug returns by a hospital, health care entity, or charitable institution conducted under 21 CFR 203.23;
(12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use;
(13) the distribution of prescription drugs by the original manufacturer of the finished form of the prescription drug or the distribution of the co-licensed products by a partner of the original manufacturer of the finished form of the prescription drug; or
(14) drug returns that meet criteria established by rules adopted by the board.

SECTION 20. IC 25-26-23-9 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 9. (a) As used in this section, "unit" means a city, town, or county.
(b) A program to accept unused medication by a business or other entity that complies with applicable state and federal law is not subject to regulation by a unit.
(c) A unit may not do any of the following:
   (1) Impose a tax, fee, assessment, or charge on a consumer, business, or other entity to pay for or support a program to accept unused medication in the unit's jurisdiction.
   (2) Require a business or other entity to establish, pay for, or operate a program to accept unused medication in the unit's jurisdiction.
   (d) Nothing in this section prohibits a unit from using money in the unit's general fund to operate a program to accept unused medication.

SECTION 21. IC 25-26-24-2.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 2.5. As used in this chapter,
"controlled substance" has the meaning set forth in IC 35-48-1-9. The term includes gabapentin.

SECTION 22. IC 25-26-24-26 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE APRIL 18, 2019 (RETROACTIVE)]: Sec. 26. Any administrative rule adopted under IC 35-48-7-12.1 (before its repeal) is hereby considered to be adopted under section 22 of this chapter.

SECTION 23. IC 27-1-37.4-8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2019]: Sec. 8. (a) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under a health plan, the order in which certain prescription drugs must be used to treat a covered individual's condition.

(b) A health plan that denies prior authorization for a prescription drug described in subdivision (1) or (2) shall provide, in the notice of denial, an alternative list of prescription drugs or alternative treatments as follows:

(1) If:

(A) the prescription drug is not included in the health plan's formulary; and
(B) there is at least one (1) alternative prescription drug in the same therapeutic classification (as defined in IC 12-15-35-17.5);

the alternative list must specify the alternative prescription drugs described in clause (B) that are covered by the health plan.

(2) If the prescription drug is prescribed to treat a condition for which coverage under the health plan requires use of a step therapy protocol, the alternative list must specify the alternative prescription drugs or alternative treatments that are required by the step therapy protocol.

SECTION 24. [EFFECTIVE UPON PASSAGE] (a) The Indiana board of veterinary medical examiners shall study the regulation of veterinary technicians and submit a report to the legislative council in an electronic format under IC 5-14-6 before November 1, 2019.

(b) This SECTION expires January 1, 2020.

SECTION 25. An emergency is declared for this act.