First Regular Session of the 123rd General Assembly (2023)

HOUSE ENROLLED ACT No. 1445

AN ACT to amend the Indiana Code concerning human services.

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

SECTION 1. IC 12-15-13.6-1, AS ADDED BY P.L.196-2021, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 1. **(a)** Once every three (3) state fiscal years:

(1) the state board of accounts; or

(2) an independent auditor with experience auditing expenses related to prescription drugs that is hired by the state board of accounts;

shall conduct an audit examining prescription drug cost sharing for the Medicaid program.

(b) The attorney general may, for an audit described under IC 27-1-3.7, issue a request for proposal under IC 27-1-3.7 to evaluate and determine whether to include the following in the request for proposal for the audit:

(1) Cost sharing.

(2) Spread pricing.

(3) Patient steering.

(4) Proper brand and generic definitions.

(5) Effective rate clawbacks.

(6) Medical loss ratio inflation.

(7) Formulary compliance.

(8) Discriminatory pricing.

(9) Specialty drug definition and categorization.

(10) Adherence to contracted pricing terms.

(11) Adherence to plan design, including:

(A) quantity limits; and

(B) prior authorization guidelines.

(12) Under market reimbursements to pharmacies.

(13) Dispensing fees.

(14) Lesser of logic pricing.

(15) Fraud, waste, and abuse.

(16) Rebates.

(17) Compliance with federal law.

(18) Review of practices of any of the following used within the Medicaid program:

(A) Managed care organizations.

(B) Pharmacies.

(C) Pharmacy services administrative organizations.

(D) Wholesalers.

(E) Drug manufacturers.

(19) Any other metric determined by the attorney general for inclusion in the audit of the Medicaid program.

This subsection expires December 31, 2025.

SECTION 2. IC 12-15-13.6-2, AS ADDED BY P.L.196-2021, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 2. **(a)** For an audit conducted under section ~~1~~ **1(a)** of this chapter, the audit look back period must be the previous three (3) state fiscal years.

(b) For an audit described in section 1(b) of this chapter, the look back period must be the previous five (5) state fiscal years. This subsection expires December 31, 2025.

SECTION 3. IC 12-15-13.6-4, AS ADDED BY P.L.196-2021, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 4. **(a)** The results of an audit conducted under section ~~1~~ **1(a)** of this chapter must be provided to the office of the secretary.

(b) Before September 1, 2024, the results of an audit conducted under IC 27-1-3.7 and section 1(b) of this chapter must be provided to the interim study committee on public health, behavioral health, and human services established by IC 2-5-1.3-4. This subsection expires December 31, 2025.

SECTION 4. IC 12-23-20-2, AS AMENDED BY P.L.32-2021, SECTION 32, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2023]: Sec. 2. (a) This section does not apply to a health care provider providing services in any of the following:

(1) An adult or juvenile correctional facility operated by the state or a local unit.

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

(3) A facility that is certified by the division.

(4) An opioid treatment program that has been certified or licensed by the division under IC 12-23-18.

(5) A state institution.

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

(7) The Indiana Veterans' Home.

(b) A physician who is providing office based opioid treatment or who is acting in a supervisory capacity to other health care providers that are providing office based opioid treatment must:

(1) have ~~both:~~

~~(A)~~ ~~a waiver from the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and meet the qualifying standards required to treat opioid addicted patients in an office based setting; and~~

~~(B)~~ a valid federal Drug Enforcement Administration registration number and identification number; ~~that specifically authorizes treatment in an office based setting;~~ and

(2) abide by all:

(A) federal; and

(B) state;

laws and regulations concerning the prescribing of medications.

(c) A health care provider that prescribes for a patient in an office based opioid treatment setting shall do and document the following:

(1) Determine the patient's age.

(2) Perform an initial assessment and a physical examination as appropriate for the patient's condition and the health care provider's scope of practice and obtain a medical history of the patient before treatment begins.

(3) Obtain substance use history and any substance use disorder diagnosis of the patient.

(4) Perform a mental health assessment.

(5) Obtain informed consent for treatment and establish a treatment agreement with the patient that meets the requirements set forth in subsection (d).

(6) If determined appropriate, prescribe office based opioid treatment for the patient and require office visits of the patient in person throughout treatment.

(7) Evaluate the patient's progress and compliance with the treatment agreement and document the patient's progress with the

treatment plan.

(8) Perform toxicology screening for the following in accordance with rules adopted under IC 25-22.5-2-7(a)(14) in order to assess medication adherence and to screen for other substances:

(A) Stimulants.

(B) Alcohol.

(C) Opioids, including:

(i) oxycodone;

(ii) methadone; and

(iii) buprenorphine.

(D) Tetrahydrocannabinol.

(E) Benzodiazepines.

(F) Cocaine.

(9) Review INSPECT (as defined in IC 25-26-24-7) concerning controlled substance information for the patient before induction and at least four (4) times per year during treatment.

(10) If the patient is a female and has child bearing potential:

(A) perform a pregnancy test at the onset of treatment;

(B) counsel the patient about the risks of treatment to a fetus, including fetal opioid dependency and neonatal abstinence syndrome; and

(C) provide for or refer the patient to prenatal care, if the pregnancy test performed under clause (A) is positive.

(11) Prescribe an overdose intervention drug and education on how to fill the prescription when buprenorphine is initiated on the patient.

(12) Provide for an ongoing component of psychosocial supportive therapy, with direction from the health care provider on the amount of the therapy.

(d) The treatment agreement required in subsection (c)(5) must include at least the following:

(1) The goals of the treatment.

(2) The patient's consent to drug monitoring testing.

(3) The prescriber's prescribing policies that include at least the following:

(A) A requirement that the patient take the medication as prescribed.

(B) A prohibition on sharing or selling the medication.

(C) A requirement that the patient inform the prescriber about any:

(i) other controlled substances or other medication prescribed or taken by the patient; and

(ii) alcohol consumed by the patient.

(4) The patient's consent to allow the prescriber to conduct random pill counts for prescriptions.

(5) Reasons that the office based opioid treatment of the patient may be changed or discontinued by the prescriber.

The provider shall maintain a copy of the informed consent for treatment in the patient's medical record.

(e) During the examinations required by subsection (c)(6), the prescriber shall do the following:

(1) Evaluate and document patient progress and compliance with the patient's treatment plan.

(2) Document in the patient's medical record whether the patient is meeting treatment goals.

(3) Discuss with the patient the benefits and risks, if relevant, of ongoing buprenorphine treatment.

(f) If a toxicology screening described in subsection (c)(8) shows an absence of a prescribed drug, the provider must discuss and implement a plan with the patient to optimize medication adherence and schedule an earlier follow up appointment with the patient. The provider shall document the discussion in the patient's medical record.

(g) If a toxicology screening described in subsection (c)(8) shows a presence of an illegal or nonprescribed drug, the provider shall assess the risk of the patient to be successfully treated and document the results in the patient's medical record.

(h) The provider may perform a subsequent confirmation toxicology screening of the patient if the provider considers it medically necessary or to clarify an inconsistent or unexpected toxicology screening result.

SECTION 5. IC 25-26-24-19, AS ADDED BY P.L.51-2019, SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2023]: Sec. 19. (a) Information received by the INSPECT program under section 17 of this chapter is confidential.

(b) The board shall carry out a program to protect the confidentiality of the information described in subsection (a). The board may disclose the information to another person only under subsection (c), (d), or (g).

(c) The board may disclose confidential information described in subsection (a) to any person who is authorized to engage in receiving, processing, or storing the information.

(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons:

(1) A member of the board or another governing body that licenses practitioners and is engaged in an investigation, an

adjudication, or a prosecution of a violation under any state or federal law that involves ephedrine, pseudoephedrine, or a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution;

of a violation under any state or federal law that involves ephedrine, pseudoephedrine, or a controlled substance.

(3) A law enforcement officer who is an employee of:

(A) a local, state, or federal law enforcement agency; or

(B) an entity that regulates ephedrine, pseudoephedrine, or controlled substances or enforces ephedrine, pseudoephedrine, or controlled substances rules or laws in another state;

that is certified to receive ephedrine, pseudoephedrine, or controlled substance prescription drug information from the INSPECT program.

(4) A practitioner or practitioner's agent certified to receive information from the INSPECT program.

(5) An ephedrine, pseudoephedrine, or controlled substance monitoring program in another state with which Indiana has established an interoperability agreement.

(6) The state toxicologist.

(7) A certified representative of the Medicaid retrospective and prospective drug utilization review program.

(8) A substance abuse assistance program for a licensed health care provider who:

(A) has prescriptive authority under this title; and

(B) is participating in the assistance program.

(9) An individual who holds a valid temporary medical permit issued under IC 25-22.5-5-4 or a noneducational commission for foreign medical graduates certified graduate permit issued under IC 25-22.5-5-4.6.

(10) A county coroner conducting a medical investigation of the cause of death.

(11) The management performance hub established by IC 4-3-26-8.

(12) The state epidemiologist under the ~~state~~ **Indiana** department of health.

(e) Information provided to a person under:

(1) subsection (d)(3) is limited to information:

(A) concerning an individual or proceeding involving the unlawful diversion or misuse of a schedule II, III, IV, or V controlled substance; and

(B) that will assist in an investigation or proceeding;

(2) subsection (d)(4) may be released only for the purpose of:

(A) providing medical or pharmaceutical treatment; or

(B) evaluating the need for providing medical or pharmaceutical treatment to a patient; and

(3) subsection (d)(11) must be released to the extent disclosure of the information is not prohibited by applicable federal law.

(f) Before the board releases confidential information under subsection (d), the applicant must be approved by the INSPECT program in a manner prescribed by the board.

(g) The board may release to:

(1) a member of the board or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive ephedrine, pseudoephedrine, or controlled substance prescription drug information; and

(B) approved by the board to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(h) The information described in subsection (g) may not be released until it has been reviewed by:

(1) a member of the board who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the board's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (i).

(i) An investigator or a law enforcement officer receiving

confidential information under subsection (c), (d), or (g) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

(1) A proceeding under IC 16-42-20.

(2) A proceeding under any state or federal law.

(3) A criminal proceeding or a proceeding in juvenile court.

(j) The board may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering ephedrine, pseudoephedrine, or a controlled substance. Statistical reports compiled under this subsection are public records.

(k) Except as provided in ~~subsection~~ **subsections** (q) **and (r),** and in addition to any requirements provided in IC 25-22.5-13, the following practitioners shall obtain information about a patient from the data base either directly or through the patient's integrated health record before prescribing an opioid or benzodiazepine to the patient:

(1) A practitioner who has had the information from the data base integrated into the patient's electronic health records.

(2) A practitioner who provides services to the patient in:

(A) the emergency department of a hospital licensed under IC 16-21; or

(B) a pain management clinic.

(3) Beginning January 1, 2020, a practitioner who provides services to the patient in a hospital licensed under IC 16-21.

(4) Beginning January 1, 2021, all practitioners.

However, a practitioner is not required to obtain information about a patient who is subject to a pain management contract from the data base more than once every ninety (90) days.

(l) A practitioner who checks the INSPECT program either directly through the data base or through the patient's integrated health record for the available data on a patient is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner:

(1) seeking information from the INSPECT program; and

(2) in good faith using the information for the treatment of the patient.

The civil immunity described in this subsection does not extend to a practitioner if the practitioner receives information directly from the INSPECT program or through the patient's integrated health record and then negligently misuses this information. This subsection does not apply to an act or omission that is a result of gross negligence or intentional misconduct.

(m) The board may review the records of the INSPECT program. If

the board determines that a violation of the law may have occurred, the board shall notify the appropriate law enforcement agency or the relevant government body responsible for the licensure, regulation, or discipline of practitioners authorized by law to prescribe controlled substances.

(n) A practitioner who in good faith discloses information based on a report from the INSPECT program either directly through the data base or through the patient's integrated health record to a law enforcement agency is immune from criminal or civil liability. A practitioner that discloses information to a law enforcement agency under this subsection is presumed to have acted in good faith.

(o) A practitioner's agent may act as a delegate and check INSPECT program reports on behalf of the practitioner.

(p) A patient may access a report from the INSPECT program that has been included in the patient's medical file by a practitioner.

(q) A practitioner is not required under subsection (k) to obtain information about a patient from the data base or through the patient's integrated health record before prescribing an opioid or benzodiazepine if any of the following apply:

(1) The practitioner has obtained a waiver from the board because the practitioner does not have access to the Internet at the practitioner's place of business.

(2) The patient is:

(A) recovering; or

(B) in the process of completing a prescription that was prescribed by another practitioner;

while still being treated as an inpatient or in observation status.

(3) The data base described in section 18 of this chapter is suspended or is not operational if the practitioner documents in writing or electronically the date and time in the patient's medical record that the practitioner, dispenser, or delegate attempted to use the data base.

(r) A practitioner is not required under subsection (k) to obtain information about a patient from the data base or through the patient's integrated health record before prescribing an opioid or benzodiazepine if the patient is enrolled in a hospice program (as defined in IC 16-25-1.1-4).

SECTION 6. IC 27-1-3.7 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]:

Chapter 3.7. Audit of Pharmacy Benefit Managers Contracted with the State

Sec. 1. As used in this chapter, "Medicaid audit" refers to the audit required by IC 12-15-13.6-1(b).

Sec. 2. As used in this chapter, "state employee health plan" refers to the following plans that provide coverage for prescription drugs:

(1) A self-insurance program established under IC 5-10-8-7(b).

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under IC 5-10-8-7(c).

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

Sec. 3. (a) Before September 1, 2023, the attorney general may issue a request for proposal for a state employee health plan audit and a Medicaid audit. The attorney general may evaluate and determine whether to include the following in the request for proposal in the audit of prescription drugs:

(1) Prescription drug cost sharing.

(2) Spread pricing.

(3) Patient steering.

(4) Proper brand and generic definitions.

(5) Effective rate clawbacks.

(6) Medical loss ratio inflation.

(7) Formulary compliance.

(8) Discriminatory pricing.

(9) Specialty drug definition and categorization.

(10) Adherence to contracted pricing terms.

(11) Adherence to plan design, including:

(A) quantity limits; and

(B) prior authorization guidelines.

(12) Under market reimbursements to pharmacies.

(13) Dispensing fees.

(14) Lesser of logic pricing.

(15) Fraud, waste, and abuse.

(16) Rebates.

(17) Compliance with federal law.

(18) Review of practices of any of the following used by the state employee health plan or the Medicaid program:

(A) Managed care organizations.

(B) Pharmacies.

(C) Pharmacy services administrative organizations.

(D) Wholesalers.

(E) Drug manufacturers.

(19) Any other metric determined by the attorney general.

(b) The attorney general may consult with the state personnel department and the office of the secretary of family and social services in:

(1) developing the request for proposal; and

(2) awarding the contract.

(c) If the attorney general decides to issue a request for proposal under this chapter, the attorney general shall develop the request for proposal in a manner that would begin the audit before February 1, 2024.

(d) Any contract between the state personnel department or the office of the secretary of family and social services for the administration of prescription drugs must include a provision to require the person to cooperate with an audit conducted under this chapter and provide the required information to the person awarded the contract for the audit.

Sec. 4. (a) For an audit conducted under this chapter, the audit look back period must be the previous five (5) state fiscal years.

(b) The:

(1) state personnel department;

(2) office of the secretary of family and social services; and

(3) private agency, business firm, limited liability company, or corporation with which the state personnel department or the office of the secretary has contracted for administrative services;

shall provide the necessary data to the auditor to complete an audit described in this chapter.

Sec. 5. Before September 1, 2024, the attorney general shall provide the results of an audit conducted under this chapter to the interim study committee on public health, behavioral health, and human services established by IC 2-5-1.3-4 in an electronic format under IC 5-14-6.

Sec. 6. This chapter expires December 31, 2025.

SECTION 7. **An emergency is declared for this act**.

Speaker of the House of Representatives

President of the Senate

President Pro Tempore

Governor of the State of Indiana

Date: _____ Time: _____