SENATE ENROLLED ACT No. 214

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 12-15-35-35 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 35. (a) **Except as provided in IC 12-15-35.5-9,** before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least fifteen (15) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least fifteen (15) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(b) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(c) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

SECTION 2. IC 12-15-35.5-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 9. (a) The office may not reimburse under Medicaid for Subutex, Suboxone, or a similar trade name or generic of the drug if the drug is only indicated for addiction treatment and was prescribed for the treatment of pain or pain management.**

SECTION 3. IC 12-23-20 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE

JULY 1, 2016]:

Chapter 20. Opioid Treatment Providers

Sec. 1. (a)This section applies to an office based opioid treatment provider who:

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

(2) has a valid federal Drug Enforcement Administration registration number and identification number that specifically authorizes treatment in an office based setting.

(b) The office of the secretary and the division shall develop a treatment protocol containing best practice guidelines for the treatment of opiate dependent patients. The treatment protocol must require the minimal clinically necessary medication dose that includes, when appropriate, the goal of opioid abstinence, and the following:

(1) Require an opioid treatment provider to periodically and randomly test a patient for the following before and during the patient's treatment by the provider:

(A) Methadone.

(B) Cocaine.

(C) Opiates.

(D) Amphetamines.

(E) Barbiturates.

(F) Tetrahydrocannabinol.

(G) Benzodiazepines.

(H) Any other suspected or known drug that may have been abused by the patient.

(2) Require that if a patient tests positive under a test described in subdivision (1) for:

(A) a controlled substance other than a drug for which the patient has a prescription or that is part of the patient's treatment plan with the provider; or

(B) an illegal drug other than the drug that is part of the patient's treatment plan with the provider;

the opioid treatment provider and the patient shall review the treatment plan and consider changes with the goal of opioid abstinence.

(3) Require that an opioid treatment provider must determine that the benefit to the patient in receiving the take home opioid treatment medication outweighs the potential risk of

diversion of the take home opioid treatment medication.

(4) Develop clinical standards for:

(A) the appropriate tapering of a patient on and off an opioid treatment medication;

(B) relapse; and

(C) overdose prevention.

(5) Develop standards and protocols for an opioid treatment provider to do the following:

(A) Assess new opioid treatment patients to determine the most effective opioid treatment medications to start the patient's opioid treatment.

(B) Ensure that each patient voluntarily chooses maintenance treatment and that relevant facts concerning the use of opioid treatment medications, including nonaddictive medication options, are clearly and adequately explained to the patient.

(C) Have appropriate opioid treatment patients who are receiving maintenance medications for opioid treatment move to receiving other approved opioid treatment medications.

(c) Before December 31, 2016, the office of the secretary shall recommend the best practice guidelines required under subsection (b) to:

(1) the Indiana professional licensing agency established under IC 25-1-5;

(2) the office; and

(3) a managed care organization that has contracted with the office.

President of the Senate

President Pro Tempore

Speaker of the House of Representatives

Governor of the State of Indiana

Date: _____ Time: _____