



Indiana State Monitor

State Overview Relating to Prescribing of Controlled Substances to Treat Pain and Clinical Drug Testing

Does Indiana have a Prescription Drug Monitoring Program?

Yes. This program is robust and the program's website has a great deal of helpful information relating to usage guidelines. For example, only health practitioners who are licensed to prescribe or dispense controlled substances in the United States may establish an INSPECT account and request an INSPECT Patient Rx History Report. A registered account holder may certify whomever they choose to serve as their agent for purposes of submitting requests to INSPECT; however, any misuse or illicit activity found to be occurring with an account is the sole responsibility of the account holder.

The program's Patient Rx History Report provides an overview of a patient's prescription activity over a certain period of time. There is often a lag of up to two (2) weeks before the prescription data is available for review. Many prescriptions dispensed on an outpatient basis at hospital pharmacies or doctors' offices may not be present on Rx History Reports. Health Practitioners may only request reports on patients for whom they are providing treatment or evaluating the need for treatment. This includes patients who have made appointments for an initial office visit or persons who have presented a prescription to a pharmacist. Health Practitioners may not request a report on office/pharmacy staff, prospective employees or anyone else for whom there is no medical chart/record available on-site for review at the practitioner's office/pharmacy location. Reports must be used only for purposes of making medical treatment decisions. Users should always take steps to verify that the information contained in the report is accurate. The report should be one factor in a comprehensive assessment of a patient. The information contained in the Patient Rx History Report is privileged medical treatment information and must not be discussed with anyone who is not involved in the direct provision of medical treatment for the patient. Practitioners may contact other health providers to discuss the care of a mutual patient. If another provider wishes to have a copy of the INSPECT Patient Rx History Report, they should establish an account and submit a request for their own copy of the report. The report, or the contents of the report, should never be faxed, mailed, emailed or otherwise disseminated. Practitioners must not provide a copy of the report to the patient.

On matters related to the sharing of a Patient Rx History Report with law enforcement, please consult with the appropriate professional association for additional guidance. If the INSPECT Patient Rx History Report is stored along with a patient's other medical records, it must be clearly marked "Do Not Copy." It should never be included when sending a patient's medical records to another health provider. Resource: IC-35-48-7-11.1



Does Indiana have a Pain Clinic Registration Act? Are there specific standards for pain clinics on drug testing? Are there general pain management standards that make suggestions about drug testing?

No. Indiana does not have a pain clinic registration act. **The Indiana Professional Licensing Agency (IPLA) through the Medical Licensing Board (MLB) adopted emergency rules in October 2013, relating to the prescribing of opioids.** The final proposed drafts of these rules were released September 3, 2014, and are scheduled to take effect November 1, 2014. The rules continue to require doctors who prescribe opioids to patients at certain levels for more than three consecutive months to take additional evaluation and compliance steps. The rules specifically state what must be included in the initial evaluation and risk stratification of the patient, as well as informed consent. Clinicians are required to enter into a written treatment agreement with patients on chronic opioid therapy, to see the patient at least every four months, if not more frequently, and to run and review INSPECT reports and drug tests, both initially and annually. Exemptions exist in the rule for patients with a terminal medical condition, residents of an Indiana-licensed health facility, patients enrolled in an Indiana-licensed hospice program, and patients enrolled in an inpatient or outpatient palliative care program of an Indiana-licensed hospital or hospice.

The rules also contain very specific drug monitoring requirements, the provisions of which do not go into effect until January 1, 2015:

- (a) *After December 31, 2014, at any time the physician determines that it is medically necessary, whether at the outset of an opioid treatment plan, or any time thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test, on the patient.*
- (b) *In determining whether a drug monitoring test under subsection (a) is medically necessary, the physician shall consider the following factors:*
 - (1) *Whether there is reason to believe a patient is not taking the prescribed opioids or is diverting the opioids.*
 - (2) *Whether there has been no appreciable impact on the patient's chronic pain despite being prescribed opioids for a period of time that would generally have an impact.*
 - (3) *Whether there is reason to believe the patient is taking or using controlled substances other than opioids or other drugs or medications including illicit street drugs that might produce significant polypharmacological effects or have other detrimental interaction effects.*
 - (4) *Whether there is reason to believe the patient is taking or using opioids in addition to the opioids being prescribed by the physician and any other treating physicians.*

- (5) Attempts by the patient to obtain early refills of opioid containing prescriptions.
 - (6) The number of instances in which the patient alleges that their opioid containing prescription has been lost or stolen.
 - (7) When the patient's INSPECT report provides irregular or inconsistent information.
 - (8) When a previous drug monitoring test conducted on the patient raised concerns about the patient's usage of opioids.
 - (9) Necessity of verifying that the patient no longer has substances in the patient's system that are not appropriate under the patient's treatment plan.
 - (10) When the patient engages in apparent aberrant behaviors or shows apparent intoxication.
 - (11) When the patient's opioid usage shows an unauthorized dose escalation.
 - (12) When the patient is reluctant to change medications or is demanding certain medications.
 - (13) When the patient refuses to participate in or cooperate with a full diagnostic workup or examination.
 - (14) Whether a patient has a history of substance abuse.
 - (15) When the patient has a health status change (for example, pregnancy).
 - (16) Co-morbid psychiatric diagnoses.
 - (17) Other evidence of chronic opioid use, controlled substance abuse or misuse, illegal drug use or addiction or medication noncompliance.
 - (18) Any other factor the physician believes is relevant to making an informed professional judgment about the medical necessity of a prescription.
- (c) Nothing about subsection (b) shall be construed to prohibit the physician from performing or ordering a drug monitoring test at any other time the physician considers appropriate.
- (d) If the test required under subsection (a), or conducted under subsection (c), reveals inconsistent medication use patterns or the presence of illicit substances, a review of the current treatment plan shall be required. Documentation of the revised treatment plan and discussion with the patient must be recorded in the patient's chart.
- (Reference: Medical Licensing Board of Indiana; 844 IAC 5-6-9)

Indiana practitioners should consult with an experienced health care attorney to determine whether other Indiana regulations impact controlled substance prescribing and to discuss the current status of the drug testing component of these rules. The Indiana Office of the Attorney General also publishes an educational toolkit ("First Do no Harm" via "Bitter Pill" website) on opioid prescribing, and it contains references drug testing.

Does Indiana have guidance on the Treatment of Opioid Addiction in the Medical Office? Do these materials make reference to drug testing as part of the patient treatment plan?

No. However, Indiana has legislation pending that would, under an amendment to [440 IAC 10-4-19](#), require the physician to list other medications as alternatives to methadone that may be used by opioid treatment programs to treat patients and require the program physician to check the Indiana INSPECT program prior to administering any opioid treatment medications, to document the findings in the patient's record, and to explain to the patient the risks and benefits of treatment medication and relevant facts concerning the use of opioid treatment medications to ensure that the patient voluntarily chooses maintenance treatment. Additional pending changes are proposed. Indiana prescribers may wish to consult the FSMB's 2013 Model Policy on this topic. These materials contain multiple references to clinical drug testing in this patient population. The Indiana State Medical Society recently published a set of guidelines on pain management for the Emergency Department.

IMPORTANT NOTICE TO READERS:

This document is not intended to impart any legal advice. The document is intended to be educational and readers are encouraged to review this information with qualified legal counsel before taking any action relative to controlled substance prescribing and clinical drug testing.

Quick Links & Resources - Indiana Materials

Indiana Professional Licensing Agency
<http://www.in.gov/pla/medical.htm>

Indiana "Bitter Pill" Toolkit
<http://www.in.gov/bitterpill/toolkit.html>

Indiana Prescription Monitoring Program (INSPECT)
<http://www.in.gov/pla/inspect/>

Indiana State Medical Association
<http://www.ismanet.org/index.html>

Federation of State Medical Boards
<http://www.fsmb.org/>

Federation of State Medical Boards Model Policy on the Use of Opioid Analgesics for the Treatment of Chronic Pain
http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf

Federation of State Medical Boards Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office
http://library.fsmb.org/pdf/2013_model_policy_treatment_opioid_addiction.pdf