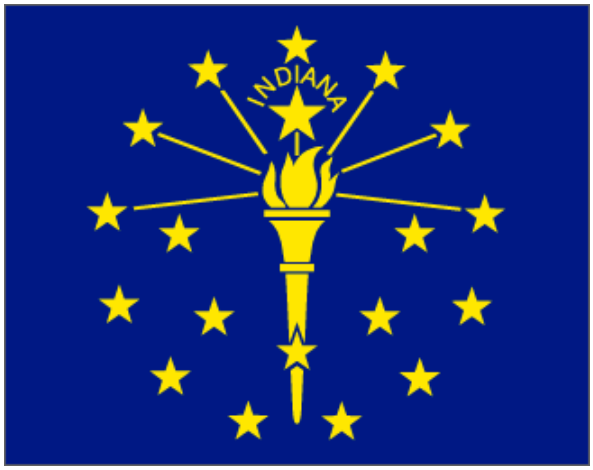
Prescribing and Dispensing Profile

Indiana



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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

Schedule II substances may only be dispensed on the written prescription of a practitioner

- Except that emergency dosages of medically necessary medications for a period not to exceed 48 hours may be dispensed by or on the direction of a practitioner
- May be dispensed on the oral prescription of a practitioner in emergency situations
  - Must be promptly reduced to writing
  - Must be limited to an amount adequate to treat the patient during the emergency period
  - If the prescribing practitioner isn't known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using the phone number listed in the telephone directory or other good faith efforts to assure his or her identity
  - Must cause a written prescription to be delivered to the pharmacy within seven days
  - Emergency situation means those situations in which the prescribing practitioner determines the following:
    - Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user
    - No appropriate alternative treatment is available, including administration of a drug that is not a Schedule II substance
    - It is not reasonably possible for the prescribing practitioner to provide a written prescription prior to the dispensing
- May be dispensed on the faxed prescription of a practitioner in the following circumstances:
  - For administration of narcotic substances to be compounded for direct administration to a patient in a private residence, long-term care facility, or hospice by certain methods
  - For patients in a hospice program or long term care facility

Schedule II prescriptions shall be kept in a separate file from other prescriptions

Schedule II prescriptions cannot be refilled

Schedule III, IV and V Prescribing Limitations (not related to pain clinics)

Schedule III—V substances can only be dispensed on the written, faxed, electronic, or oral prescription of a practitioner

- Emergency dosages of medically necessary medications for a period not to exceed 48 hours may be dispensed by or on the direction of a practitioner

Schedule V substances shall not be distributed or dispensed other than for a medical purpose

Schedule III—V prescriptions shall be kept in a separate file from other prescriptions

Schedule III and IV prescriptions shall not be filled or refilled more than six months after originally written or refilled more than five times unless renewed by the practitioner

Schedule V prescriptions may only be refilled as expressly authorized by the prescriber on the prescription

Miscellaneous Prescribing/Dispensing Requirements

If prescribing methadone for a patient for the treatment of pain or pain management, the prescriber shall include on the prescription or order that the prescription is for the treatment of pain

Except in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority practicing in accordance with standard care arrangements, a physician shall not prescribe, dispense, or otherwise provide or cause to be provided, any controlled substance or legend drug that is not a controlled substance to a person who the physician has never personally physically examined and diagnosed

- May prescribe, dispense, or otherwise provide or cause to be provided a legend drug that is not a controlled substance to a person if the physician is providing care in consultation with another physician who has an ongoing professional relationship with the patient and who has agreed to supervise the patient's use of the drug or drugs to be provided
- The above prohibition does not apply to or prohibit the following:
  - Provision of drugs to a person admitted as an inpatient to or is a resident of an institutional facility
  - Provision of controlled substances or legend drugs by emergency medical squad personnel, nurses, or other appropriately trained and licensed individuals

Prescriptions must contain the following information:

- Date and signature of prescriber
- Name and address of patient
- Name, address, and federal registration number of prescriber

Prescribing/Dispensing Limitations for Dentists

Licensed pharmacists in Indiana may fill prescriptions of licensed dentists of Indiana for any drug necessary in the practice of dentistry

Prescribing/Dispensing Limitations for Optometrists

Optometrists may prescribe, administer, or dispense legend drugs, but not controlled substances, if certified by law to do so

Pain Clinic/Pain Management Regulations

Rules for the use of opioids for chronic pain management do not apply to patients with a terminal condition, residents of a health facility, patients enrolled in a hospice program, and patients enrolled in an inpatient or outpatient palliative care program of a licensed hospital or licensed hospice program

The requirements only apply if a patient has been prescribed:

- More than 60 opioid containing pills a month for more than three consecutive months
- A morphine equivalent dose of more than 15mg per day for more than three consecutive months
- A transdermal opioid patch for more than three consecutive months
- At any time it is classified as a controlled substance under Indiana law, tramadol, but only if the patient's tramadol dose reaches a morphine equivalent dose of more than 60mg per day for more than three consecutive months
- A hydrocodone only extended release medication that is not in an abuse deterrent form

The physician shall do the following in an initial evaluation of the patient:

- Perform a history and physical exam and obtain or order appropriate tests as indicated
- Make a diligent effort to obtain and review records from previous health care providers to supplement the physician's understanding of the patient's chronic pain problem, including past treatments, and documenting this effort
- Ask the patient to complete an objective pain assessment tool to document and better understand the patient's specific pain concerns
- Assess both the patient's mental health status and risk for substance abuse using available validated screening tools
- After completing the initial evaluation, establish a working diagnosis and tailor a treatment plan to meaningful and functional goals with the patient reviewing them from time to time

Where medically appropriate, the physician shall utilize non-opioid options instead of or in addition to prescribing opioids

Physician shall discuss the potential risks and benefits of opioid treatment for chronic pain, as well as expectations related to prescription requests and proper medication use and shall:

- Where alternative modalities to opioids for managing pain exist for a patient, discuss them with the patient
- Provide a simple and clear explanation to help patients understand the key elements of the treatment plan
- Counsel women between 14 and 55 years of age with child bearing potential about the risks to the fetus when the mother has been taking opioids while pregnant including fetal dependency and neonatal abstinence syndrome
- Discuss the risks of dependency and addiction
- Discuss safe storage practices for prescribed opioids
- Provide a written warning to the patient disclosing the risks associated with taking extended release medications that are not in an abuse deterrent form, if the physician prescribes for the patient a hydrocodone only extended release medication that is not in an abuse deterrent form

Pain Clinic/Pain Management Regulations, cont'd.

- Review a treatment agreement with the patient that includes at least the following:
  - The goals of treatment
  - The patient's consent to drug monitoring testing in circumstances where the physician determines that drug monitoring testing is medically necessary
  - The physician's prescribing practices, which must include at least:
    - A requirement that the patient take the medication as prescribed
    - A prohibition of sharing medication with other individuals
  - A requirement that the patient inform the physician:
    - About any other controlled substances prescribed or taken by the patient
    - If the patient drinks alcohol while taking opioids
  - The granting of permission to the physician to conduct random pill counts
  - Reasons the opioid therapy might be discontinued or changed by the physician

Physicians shall not prescribe opioids for patients without periodic scheduled visits

- Visits for patients with a stable medical condition and treatment plan shall occur face to face at least once every four months
  - More frequent visits may be appropriate for patients working with the physician to achieve optimal management
- For patients requiring changes to the medication and treatment plan, if changes are prescribed by the physician, the visits required by this subsection shall be scheduled at least once every two months until the medication and treatment have been stabilized
- Physician shall evaluate the patient at each visit for progress and compliance with the treatment plan and set clear expectations along the way, such as attending physical therapy, counseling, and other treatment options

At the outset of an opioid treatment plan and annually thereafter, a physician prescribing opioids for a patient shall run an INSPECT report on that patient and document whether the report is consistent with the physician's knowledge of the patient's controlled substance use history

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 drug testing, which must include a confirmatory test using a method selective enough to differentiate individual drugs within a drug class

- In determining whether drug testing is medically necessary, the physician shall consider each of the following factors where applicable and reasonably feasible:
  - Whether there is reason to believe a patient is not taking the prescribed opioids or is diverting them
  - Whether there has been no appreciable impact on the patient's chronic pain despite being prescribed opioids for a period of time during which there would generally have been an impact
  - 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 interactions
  - 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

Pain Clinic/Pain Management Regulations, cont'd.

- Attempts by the patient to obtain early refills of opioids
- The number of instances in which the patient alleges that their prescription has been lost or stolen
- When the patient's INSPECT report provides irregular or inconsistent information
- When a previous drug test raised concern
- 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
- When the patient engages in apparent aberrant behaviors or shows apparent intoxication
- When the patient's opioid usage shows an unauthorized dose escalation
- When the patient is reluctant to change medication or is demanding certain medications
- When the patient refuses to participate in or cooperate with a full diagnostic workup or examination
- Whether the patient has a history of substance abuse
- Whether the patient has a health status change
- Co-morbid psychiatric diagnosis
- Other evidence of chronic opioid use, controlled substance use or misuse, illegal drug use or addiction, or medication noncompliance
- Any other factor the physician believes is relevant to making an informed decision about the necessity of a prescription

- If a drug test 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

When a patient's opioid dose reaches a morphine equivalent dose of more than 60mg per day, a face to face review of the treatment plan and patient evaluation must be scheduled, including consideration of a referral to a specialist

- If treatment continues with a MED of more than 60mg per day, the physician must develop a revised assessment and treatment plan for ongoing treatment which must be documented in the patient's chart, including an assessment of increased risk for adverse outcomes, including death, if the physician continues to provide ongoing opioid treatment

Training or Education Requirements or Recommendations for Practitioners who Prescribe or Dispense Controlled Substances

No specific statutes or regulations identified.

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

No specific statutes or regulations identified.

PMP Requirements for Mandatory Registration and Access

Board shall adopt regulations requiring a practitioner providing treatment for a patient at an opioid treatment program to check the PMP:

- Before initially prescribing a controlled substance to a patient
- Periodically throughout the course of treatment that uses a controlled substance

At the outset of an opioid treatment plan and annually thereafter, a physician prescribing opioids for a patient shall run an INSPECT report on that patient and document whether the report is consistent with the physician's knowledge of the patient's controlled substance use history

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

None.