Summary of New Indiana Pain Management Prescribing Rules

Created by the Indiana State Medical Association

Background
The Medical Licensing Board of Indiana adopted rules Oct. 24 that require all physicians prescribing opioids to comply, beginning Dec. 15, 2013, pursuant to Senate Enrolled Act 246.

The Prescribing Rule
Applies only to use of opioids prescribed for chronic pain management (See definitions section.)

Exclusions
The rule does not apply to:
1. Patients who are terminal (Refer to definitions section.)
2. Residents of a licensed health facility
3. Patients enrolled in a hospice program
4. Patients enrolled in inpatient or outpatient palliative care program

Thresholds
The rule applies only if a patient has been prescribed for more than three consecutive months:
1. >60 opioid-containing pills per month; or
2. A morphine equivalent dose >15 mg/day

Patient Assessment
Physicians must perform their own initial evaluations and risk stratifications of patients, including:
1. Appropriately focused H&P exams and appropriate tests, as indicated
2. Documented attempts to obtain and review records from prior providers
3. Patient-completed pain assessment tools

Patient Informed Consent
• Potential risks and benefits of opioid treatment for chronic pain
• Expectations related to prescription requests
• Proper medication use
• Alternative modalities to opioids for managing pain
• A simple and clear explanation from physicians to help patients understand the key elements of their treatment plans
• Counseling for women ages 14 to 55 of child bearing potential about risk to fetus when a mother has taken chronic opioids during pregnancy (including risk of fetal opioid dependency and neonatal abstinence syndrome)
**Patient Visits**
- No prescribing without periodic scheduled visits
- If stable meds and treatment plan, face-to-face once every four months (minimum)
- More frequent visits if still optimizing
- If still making changes to meds and treatment plan, visits every two months until stabilized (minimum)
- During visits, evaluate progress and compliance with treatment plan regularly and set clear expectations along the way (e.g., PT, counseling, other treatment)

**INSPECT Reports**
At outset of treatment plan, and at least annually thereafter, prescribing physician must run an INSPECT report and document in patient’s chart whether it is consistent with the physician’s knowledge of the patient’s controlled substance use history. (If the patient already meets the chronic pain management definition as of Dec. 14, 2013, no initial INSPECT report is required. The annual INSPECT requirement has been postponed to Nov. 1, 2014.)

**Drug Monitoring Tests**
At outset and at least annually thereafter, prescribing physician must perform a drug monitoring test that must include confirmatory test. (The initial and annual drug monitoring test requirements have been postponed to Jan. 1, 2015.) If this test is inconsistent with medication use patterns or shows illicit drugs, review treatment plan. Document the discussion and any changes in the patient chart.

**Daily High Dose Threshold**
When opioid dose reaches morphine equivalent dose of >60mg/day, a face-to-face review of treatment plan and patient evaluation must be scheduled, including consideration for a specialist referral. If physician elects to continue treating at that level, physician must develop a revised assessment plan for ongoing treatment and document in the chart, including an assessment of increased risk for adverse outcomes.

**Treatment Agreements**
With patient, review and sign a “Treatment Agreement” that must include (minimum):
1) Goals of the treatment
2) Patient’s consent to drug monitoring testing
3) Physician’s prescribing policies, including
   a) rule that patient take medication(s) as prescribed
   b) prohibition on sharing medication(s)
4) Requirement that the patient inform the physician about any other controlled substances prescribed or taken
5) Permission from the patient to the physician for conducting random pill counts.
6) Reasons the opioid therapy may be changed or discontinued by the physician.

*A copy of the agreement is retained in patient’s chart.

**Key Definitions**

**Chronic Pain** – A state in which pain persists beyond the usual course of an acute disease or healing of an injury or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

**Terminal** – A condition caused by injury, disease or illness from which, to a reasonable degree of medical certainty:
1) No recovery is expected.
2) Progression to death can be anticipated as an eventual consequence of that condition.