MEDICAL BOARD

SPECIAL ISSUE — MAY 2011

GRAND ROUNDS

YOUR REPORT FROM THE STATE MEDICAL BOARD OF OHIO

House Bill 93 – New Law to Combat Prescription Drug Abuse

Governor Kasich signed HB 93 (Prescription Drugs), on May 20, 2011. The bill goes into effect immediately. However, Section 4729.552 (C), Ohio Revised Code, related to physician ownership of pain clinics and licensure by the Ohio Board of Pharmacy, goes into effect in 30 days.

The bill, sponsored by Representatives David Burke and Terry Johnson, enables the Medical Board to more efficiently address outlier prescribing cases, and to get at the root causes of physician practices that have morphed into "pill mills."

The legislation enhances the ability of the Medical and Pharmacy Boards to take administrative action against "rogue" pain clinics by:

- Requiring licensure of facilities/practices meeting the definition of "pain management clinic" established in the bill;
- Requiring physician ownership of pain management clinics;
- Limiting the amount of controlled substances a prescriber may personally furnish to a patient, and
- Authorizing the Medical Board to adopt rules setting standards for prescribing controlled substances.

HB93 requires a facility operating as a pain management clinic to be licensed by the Pharmacy Board as a terminal distributor of dangerous drugs with a pain management classification.

HB93 also requires the physician owner/operator of a pain management clinic to supervise the activities of the clinic and the employees working at the facility. Failure to appropriately supervise employees, or failure to meet the practice and operational standards established in HB93, are grounds for disciplinary action by the Medical Board. ♦

Link to: House Bill 93, Prescription Drugs

INSIDE THIS SPECIAL ISSUE

Proposed OARRS Rule Impacts Controlled Substance Prescribers

HB93 requires the Medical Board to adopt rules establishing standards to be followed by a physician regarding the review of patient information available through OARRS. While most of the provisions in HB93 relate to physicians practicing in pain management clinics, the Medical Board's proposed rule, **4731-11-11 Standards and Procedures for Review of Ohio Automated Rx Reporting System (OARRS),** impacts all physicians who prescribe controlled substances in schedules II, III, IV, and V, and/or drugs containing carisoprodol, or tramadol.

The proposed rule sets minimum standards for obtaining and reviewing an OARRS report. The proposed rule:

- Requires a doctor to review an OARRS report, and other state's prescription monitoring program report if applicable, if the physician is aware of a patient suffering from addiction, drug abuse, or engaging in diversion of drugs, or if any of the "red flags" listed in paragraph B of this rule apply.

- Requires a physician utilizing reported drugs to treat a patient for a chronic condition or a condition that requires, or may reasonably be expected to require, more than 12 weeks of treatment with a controlled substance shall, at a minimum, request and document review of an OARRS report, and other state's prescription monitoring program report where applicable
    - At the beginning of treatment
    - Every 12 weeks
    - If any of the "red flags" listed in paragraph B of this rule apply

- Requires documentation in the medical record related to OARRS reports.

Link to: Proposed Rule 4731-11-11, Standards and Procedures for Review of OARRS

Have You Signed Up for OARRS?

Contact the Ohio Board of Pharmacy to learn how to sign up for OARRS

E-mail: info@ohiopmp.gov Phone: 614-466-4143

Defining "Pain Management Clinic"

HB93 defines a pain management clinic as a facility to which the following apply:

- A primary component of practice is treatment of pain or chronic pain;
- The majority of patients of the prescribers at the facility are provided treatment for pain or chronic pain that includes the use of controlled substances, tramadol, carisoprodol, or other drugs specified in rules adopted by the Medical Board; and
- The facility meets any other identifying criteria established in rules adopted by the Medical Board.

HB93 exempts hospitals, specified educational institutions/programs; licensed hospice programs and licensed ambulatory surgical facilities from the licensure requirement. ♦

Proposed Rule Sets Standards and Procedures for Operation of a Pain Management Clinic

HB 93 requires the Medical Board to adopt rules related to the standards and procedures for the operation of and provision of care at a pain management clinic. The law also requires the Board to establish standards and procedures to be followed by an owner in providing supervision, direction and control of individuals at a pain management clinic. Proposed rule 4731-29-01 outlines such standards.

The proposed rule requires each physician providing care at a pain management clinic to hold staff membership at a local hospital with admitting or consulting privileges and to hold board certification or meet one of the equivalencies listed in paragraph (D)(5) of the rule.

Doctors who meet the criteria listed in paragraph (D)(2) or (D)(5) of the rule are also required to complete at least 20 hours of Category I CME in pain management every two years.

Further, rule 4731-29-01 requires the physician owner of a pain management clinic to maintain a log of all patients, develop a quality assurance system, verify staff credentials on an annual basis, and maintain billing records and patient records for seven years.♦

Link to: Proposed Rule 4731-29-01, Standards and Procedures for the Operation of a Pain Management Clinic

PRACTICE POINTERS

Maintaining Records of Office-Based Opioid Treatment

Recent years have seen a dramatic increase in the number of physicians in Ohio who treat opioid addiction in the office setting using specially approved opioid products. This treatment, which requires a special federal waiver, is commonly referred to as Office-Based Opioid Treatment, or OBOT. Many physicians are not fully aware of the special federal confidentiality requirements applicable to such treatment. The State Medical Board wants to alert physicians to the importance of being aware of those confidentiality requirements.

Title 42 CFR Part 2 provides for very strict confidentiality of patient identifying information maintained by federally assisted drug and alcohol treatment programs. The confidentiality requirements of this law, which are significantly more strict than those in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), apply even to individual physicians providing OBOT. Physicians are considered to be "federally assisted" by virtue of holding DEA registration necessary to prescribe or dispense the specially approved opioid medications. Disclosures of information in violation of 42 CFR Part 2 carry criminal penalties of up to $500 on a first offense and up to $5,000 for each subsequent offense.

Physicians providing OBOT often maintain office notes, prescription details, and other records relating to the treatment as part of their general medical records for their patients. A physician can not legally provide copies of those portions of the records relating to OBOT without a special release from the patient or a court order. This is true even in response to a request from another physician involved in the patient's care, or in compliance with a subpoena.

In the course of its investigations the State Medical Board of Ohio often subpoenas patient records from physicians and facilities involved in a patient's care. Should you receive a subpoena for patient records from the Medical Board, the Board will typically not expect to receive records relating to OBOT. If the Board does require such records, we will provide you a release signed by the patient that complies with 42 CFR Part 2.

The State Medical Board commends Ohio's physicians for their willingness to provide office-based opioid treatment for opioid addiction. We encourage all physicians who provide this care to consult with their attorneys to assure that they do not inadvertently run afoul of the federal confidentiality requirements.

Proposed Rule Regarding Records of Treatment of Opioid Addiction

The Medical Board proposed **Rule 4731-11-10, Records of Treatment of Opioid Addiction** to require physicians providing office-based opioid treatment to maintain records of such treatment separate from their general medical records to comply with Federal confidentiality protections. The rule also clarifies that such records are to be disclosed to the Medical Board only with an appropriate release or court order.

Link to: Proposed Rule 4731-11-10, Records of Treatment of Opioid Addiction.

MED.OHIO.GOV

STATE MEDICAL BOARD OF OHIO

30 E. Broad St. 3rd Floor
Columbus, OH 43215-6127

Phone: 614-466-3934
Fax: 614-728-5946
Monday - Friday 8 a.m. to 5 p.m.
Closed on state and federal holidays

The Medical Board protects and enhances the health and welfare of Ohio's citizens through effective regulation of more than 62,000 licensees, including: medical doctors (MDs), doctors of osteopathic medicine (DOs), doctors of podiatric medicine and surgery (DPMs), physician assistants (PAs), massage therapists (LMTs), cosmetic therapists (CTs), anesthesiologist assistants (AAs), radiologist assistants (RAs) and acupuncturists. Naprapaths and mechanotherapists licensed before March 1992 are also overseen by the Medical Board.

COMING SOON: Look for the new **Center for Safe Prescribing** on the Medical Board's website.

We welcome your comments and suggestions regarding the newsletter. Contact us at this e-mail address:

medboardnews@med.state.oh.us.

Follow the Medical Board on FACEBOOK

THE STATE MEDICAL BOARD

PROTECTING THE PUBLIC THROUGH EFFECTIVE MEDICAL REGULATION