



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
Board of Registration in Pharmacy
239 Causeway Street, Suite 500, Boston, MA 02114

DEVAL L. PATRICK
GOVERNOR

JOHN W. POLANOWICZ
SECRETARY

CHERYL BARTLETT, RN
COMMISSIONER

Tel: 617- 973-0960

Fax 617-973-0980

www.mass.gov/dph/boards/ph

MEMO

To: Members, Board of Registration in Pharmacy
From: Vita Berg, Chief Board Counsel
Date: May 6, 2014
Re: Emergency Regulations regarding Hydrocodone-Only Extended Release Medications that are not in an Abuse Deterrent Form

Introduction

For the first time, there is an FDA-approved medication which consists entirely of hydrocodone. This hydrocodone-only extended release medication is not in an abuse-deterrent form.¹ Since the FDA-approved medication does not include abuse-deterrents in its formulation, there is an increased concern about diversion and abuse of this medication, further adding to the opioid abuse epidemic and further opioid-related overdoses.

In response to the Governor's directive, the Commissioner of DPH issued an emergency order prohibiting the prescribing and dispensing of hydrocodone-only extended release medication that is not in an abuse-deterrent form until such time as DPH determines that adequate measures to safeguard against diversion, overdose, and misuse have been implemented. See March 27, 2014 Public Health Counsel memorandum, page 2, "Actions to Address the Public Health Emergency," which is appended at Tab C. As a result, the manufacturer sought an injunction, which was granted on April 15, 2014, effective April 22, 2014, suspending the ban.

After this court decision, DPH consulted with staff of the Boards of Registration in Pharmacy and Medicine about promulgating emergency regulations to address this issue by establishing measures to safeguard against diversion, overdose, and misuse.

¹ "Abuse-deterrent formulation" means an FDA-approved formulation of a controlled substance that targets known or expected routes of abuse for that formulation.

On April 22, 2014, the Board of Registration in Medicine (“BORIM”) adopted emergency regulations regarding the prescribing of hydrocodone-only extended release medications that are not in an abuse deterrent form. The BORIM regulations require prescribers to take the following actions for each prescription of a hydrocodone-only extended release medication that is not in an abuse deterrent form:

- (a) Perform a substance abuse risk assessment and check the Prescription Monitoring Program (PMP);
- (b) Discuss the risks and benefits of the medication with the patient;
- (c) Enter into a Pain Management Treatment Agreement with the patient;
- (d) Supply a Letter of Medical Necessity that includes the patient’s diagnosis and treatment plan, verifies that other pain management treatments have failed, and indicates that a risk assessment was performed and that the licensee and the patient have entered into a Pain Management Treatment Agreement; and
- (e) Document the foregoing in the patient’s medical record.

Also on Tuesday April 22, 2014, the Commissioner of DPH issued an order requiring prescribers to utilize the PMP prior to each instance of issuing a prescription for hydrocodone-only extended release medication that is not in an abuse deterrent formulation. In Massachusetts, prescriptions for controlled substances in Schedules II and III can be written for no more a 30-day supply (MGL c. 94C, § 23(d)), so this order will require the prescriber to check the patient's PMP record at least every 30 days while he or she is being prescribed this medication.

At this time, DPH recommends that other boards of registration regulating the practice of prescribers and the Board of Registration in Pharmacy (“Board”) consider corresponding regulations. In order to safeguard patients and protect against the specific dangers presented by hydrocodone-only extended release medications that are not in an abuse deterrent form, DPH recommends that the Board to approve the amendments to 247 CMR 8.00 and 9.00, on an emergency basis.

Proposed Amendments to 247 CMR

The proposed amendments to 247 CMR 9.00 would prohibit pharmacies and pharmacists from dispensing hydrocodone-only extended release medication that is not in an abuse deterrent form unless:

- (a) the medication is dispensed in a child proof safety cap or within a locked box;
- (b) the prescriber has supplied a letter of medical necessity that complies with Board of Registration in Medicine regulations and includes the patient's diagnoses and treatment plan, verifies other pain management treatments have failed, and indicates that a risk assessment was performed and the prescriber and patient entered into a Pain Management Treatment Agreement;
- (c) the prescription is accompanied by a written warning that is approved by the Board regarding the specific dangers of hydrocodone-only extended release medication that is not in an abuse deterrent form; and
- (d) the pharmacist has counseled the patient regarding the use of hydrocodone-only extended release medication that is not in an abuse deterrent form.

Additionally, the proposed amendment to 247 CMR 8.00 would prohibit pharmacy technicians, pharmacy technician trainees, and pharmacy interns from handling and transporting hydrocodone-only extended release medications that are not in an abuse deterrent form and from performing data entry on hydrocodone-only extended release medications that are not in an abuse deterrent form.

Board Approval

It is respectfully requested that the Board vote to approve the Amendments to 247 CMR 8.00 and 9.00 on an emergency basis.