State of Vermont
Office of the Secretary of State

Office of Professional Regulation
89 Main Street, 3rd Floor
Montpelier, VT 05620-3402

[phone] 802-828-1505
[fax] 802-828-2465
www.sec.state.vt.us

James C. Condos, Secretary of State
Brian H. Leven, Deputy Secretary
Christopher D. Winters, Director

April 15, 2014

Dear Health Care Prescriber or Dispenser,

I am writing to you today to advise you of an Emergency Rule to tightly restrict how health care providers may prescribe certain single ingredient hydrocodone products such as Zohydro®. The Emergency Rule was released on April 3, 2014 by the Department of Health. The following is an excerpt of the announcement:

"Joined by a contingent of Vermont mayors and Health Commissioner Harry Chen, MD, Gov. Peter Shumlin announced today that the Health Department has issued an emergency rule to tightly restrict how health care providers prescribe certain hydrocodones such as Zohydro, a high-dose narcotic painkiller approved last year in a form without abuse-deterrent formulation, in controversial decision by the Food & Drug Administration (FDA). The approved drug is manufactured without an abuse-deterrent formulation (ADF) or other tamper-proofing technology. ADFs make drugs less likely to be abuse or diverted."

Among other restrictions, the new rule requires prescribers to:
- Document a thorough medical evaluation;
- Conduct and document a Risk Assessment;
- Conduct and document in the medical record a prescription of a hydrocodone without an ADF is required for the management of pain (i.e., nothing else will effectively manage the severe pain);
- Receive a signed Informed Consent form from the patient;
- Receive a Chronic Controlled Substance Treatment Agreement from the patient that shall include conditions such as urine screening, pill counts, safe storage and disposal, and other appropriate conditions as determined by the prescriber;
- Query the Vermont Prescription Monitoring System (VPMS);
- Determine a maximum daily dose, or a "not to exceed value" for the prescription to be transmitted to the pharmacy; and
- Schedule and undertake periodic follow-up visits and evaluations and referrals.

To read the complete text of the rule, visit:
http://healthvermont.gov/regs/documents/hydrocodone_emergency_rule.pdf

Sincerely,

Ronald J. Klein, RPh,
Exec. Officer, VT Brd of Pharmacy

Linda Davidson, APRN
Exec. Director, VT Brd of Nursing

VERMONT

Rule Governing the Prescription of Extended Release Hydrocodones Manufactured Without Abuse-Deterrent Formulations

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. § 102 and Act No. 75 of the Acts of the 2013 Sess. (2013) (An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse), Section 14(e).

2.0 Purpose

This rule provides requirements for the prescription of extended release hydrocodones lacking abuse-deterrent formulations in order to address potential prescription drug overdose, abuse and diversion.

3.0 Definitions

3.1 "Prescriber" means a licensed health care professional with authority to prescribe controlled substances.

3.2 "Risk Assessment" means utilizing a tool, such as the Screener and Opioid Assessment for Patients with Pain (SOAPP), designed for predicting the likelihood that a patient will abuse or misuse a prescribed controlled substance based on past behavior, genetic predispositions, social or environmental factors or other risks.

3.3 "Hydrocodone" means a semi-synthetic opioid derived from codeine.

3.4 "Controlled Substance Treatment Agreement" means a document that is agreed upon by both the prescriber and the patient acknowledging the rights, responsibilities, and risks of being on controlled substances and the treatment being received.

3.5 "Misuse" means using a controlled substance in a way that is not prescribed.

3.6 "Abuse-deterrent formulations" or "ADF" means one of the following: Physical/Chemical barriers (i.e. physical barriers that prevent chewing, crushing, cutting, grating, or grinding or chemical barriers that can resist extraction of the opioid using common solvents like water); Aversion (i.e. substances that can be combined to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or a higher dosage than directed is used); a formulation such that the drug is lacking in opioid activity until transformed in the gastrointestinal tract (known as a Prodrug); or a combination of the above methods).

4.0 Prescription of Extended Release Hydrocodones without ADFs

Prior to prescribing an extended release hydrocodone that is manufactured without an ADF, the prescriber shall:

4.1 Conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record;

4.2 Evaluate and document relative risks and benefits for the individual patient of the use of hydrocodones that are manufactured without an ADF prior to writing a prescription for such a hydrocodone. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.3;

4.3 Document in the medical record that the prescription of a hydrocodone without an ADF is required for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options, including non-pharmacological treatments, are ineffective, not tolerated, or would otherwise be inadequate to provide sufficient management of pain;

4.4 Receive a signed Informed Consent form from the patient, or if the patient is not competent to provide informed consent, from the patient's legal representative, that shall include information regarding the drug's potential for addiction, abuse, and misuse; and the risks associated with the drug of life-threatening respiratory depression; overdose as a result of accidental exposure potentially fatal especially in children; neonatal opioid withdrawal symptoms; and potentially fatal overdose when interacting with alcohol;

4.5 Receive a signed Controlled Substance Treatment Agreement from the patient that shall include requirements such as urine screening (no less frequent than every 120 days), pill counts, safe storage and disposal, and other appropriate conditions as determined by the prescriber to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance;

4.6 Query the Vermont Prescription Monitoring System (VMPS) and review other controlled substances prescribed to the patient prior to the first prescription. For any patient prescribed 40 mg or greater per day, the prescriber shall query the VPMS no less frequently than once every 120 days for as long as the patient possesses a valid prescription for that amount;

4.7 Determine a maximum daily dose, or a "not to exceed value" for the prescription to be transmitted to the pharmacy;

4.8 Write a prescription that must be filled within seven (7) days and that does not exceed 30 days in duration;

4.8 Schedule and undertake periodic follow-up visits and evaluations.

5.0 Follow-ups and Evaluation

At each follow-up visit required by Section 4.8, the prescriber shall evaluate, determine and document:

5.1 Whether to continue the treatment of pain with hydrocodones not manufactured with an ADF or whether there is an available alternative;

5.2 Whether to refer the patient for a pain management or substance abuse consultation;

5.3 A plan for the discontinuance of prescribed hydrocodone(s) if a patient has failed to adhere to the Controlled Substance Treatment Agreement.