

DEPARTMENT OF STATE
BEFORE THE SECRETARY OF STATE

In Re:	EMERGENCY RULE)	Final Order
	ADOPTION PLACING)	
	REQUIREMENTS ON)	
	PRESCRIPTION OF)	
	ER HYDROCODONE)	

WHEREAS, the Secretary of the Department of State (“the Secretary”) “may promulgate rules . . . relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this State.” 16 *Del. C.* § 4731(a); and

WHEREAS, the Secretary may adopt emergency regulations if the Secretary finds that that there exists an imminent peril to the public health, safety or welfare. 29 *Del. C.* § 10119; Regulation 9.3 of the Uniform Controlled Substance Act Regulations; and

WHEREAS, available data and information pertaining to extended-release hydrocodone lacking abuse-deterrent formulation demonstrates that this medication poses imminent peril to the public, health safety and welfare in that it is approximately five times more potent than opioids currently being prescribed to treat pain. Further, the medication lacks an abuse-deterrent formulation, meaning that it can be chewed, crushed or dissolved, thereby causing rapid release and absorption of a potentially fatal dose of hydrocodone; and

WHEREAS, the Delaware Controlled Substance Advisory Committee has recommended the enactment of an emergency regulation placing limitations and requirements on the prescription of extended-release hydrocodone lacking abuse-deterrent formulation; and

WHEREAS, the Secretary finds that adoption of the recommended regulation must occur on an emergency basis in order to properly protect the public; and

WHEREAS, the Secretary will accept, consider and respond to petitions by any interested person for the reconsideration of adoption of this regulation by addressing the same to the attention of Mr. Dave Dryden, Cannon Building, 861 Silver Lake Blvd., Dover, DE 19904; and

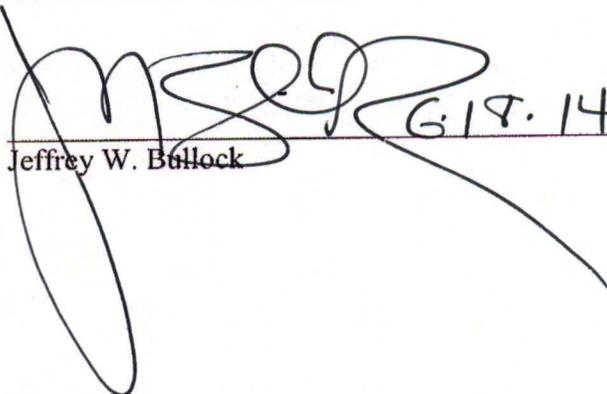
WHEREAS, a copy of this Order will be submitted to the Registrar for publication in the next issue of the Delaware Register of Regulations;

NOW, THEREFORE, IT IS ORDERED this 18th day of June, 2014:

1. The Uniform Controlled Substance Act Regulations are amended as set forth in Exhibit A, attached hereto.
2. In accordance with the provisions of 29 *Del. C.* § 10119(3), this Order shall be effective for 120 days from the date of execution.

SO ORDERED this 18th day of June 2014.

SECRETARY OF STATE


Jeffrey W. Bullock

6.18.14

EXHIBIT A

11.0 Prescription of Extended-Release Hydrocodone Lacking Abuse-Deterrent Formulation

11.1 Purpose: This rule provides requirements for the prescription of extended-release hydrocodone lacking abuse-deterrent formulation in order to address potential prescription drug overdose, abuse and diversion.

11.2 Definitions

"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); a version (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).

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

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

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

"Practitioner" means physician, dentist, veterinarian, podiatrist, nurse practitioner, physician assistant or other individual, licensed, registered, or otherwise permitted, by the United States or the State of Delaware to prescribe, dispense or store a controlled substance in the course of professional practice but does not include a pharmacist, a pharmacy, or an institutional practitioner.

"Risk Assessment" means utilizing a tool, such as the Screener and Opioid Assessment for Patients with Pain ("SOAPP"), which is 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.

11.3 Requirements

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

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

11.3.1.2 Prior to writing a prescription for a hydrocodone that is manufactured without an ADF, evaluate and document relative risks and benefits for the individual patient of the use of such a hydrocodone. The evaluation shall include, but not be limited to, a Risk Assessment as defined in Regulation 11.2;

11.3.1.3 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;

11.3.1.4 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;

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

11.3.1.6 Query the Delaware Prescription Monitoring Program ("PMP") 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 practitioner shall query the PMP no less frequently than once every 120 days for as long as the patient possesses a valid prescription for that amount;

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

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

11.3.2 The practitioner shall schedule and undertake periodic follow-up visits and evaluations of the patient.

11.3.3 The practitioner shall schedule follow-up visits with the patient and at each such visit shall evaluate, determine and document:

11.3.3.1 Whether to continue the treatment of pain with a hydrocodone not manufactured with an ADF or whether there is an available alternative;

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

11.3.3.3 A plan for the discontinuance of prescribed hydrocodone if the patient has failed to adhere to the Controlled Substance Treatment Agreement.