14-E08

VERMONT

Department of Health

Office of Legal Counsel

To: Michael Clasen, Deputy Secretary of Administration and ICAR Chair
Hon. Senator Mark MacDonald, Chair, Legislative Committee on Administrative Rules

From: David Englander, Senior Policy and Legal Advisor for the Department of Health

Date: July 24, 2014

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

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Enclosed for your review are completed administrative rule forms and text regarding an emergency rule for the Rule Governing the Prescription of Extended Release Hydrocodones Manufactured Without Abuse-Deterrent Formulations. Specifically the emergency rule conditions the prescription of such drugs in a way that takes into account the hazard those substances pose to Vermonters by means of abuse, diversion, and overdose. The Vermont Department of Health (VDH) believes it is appropriate to adopt this rule under the emergency rule provisions of Title 3 due to the imminent peril these substances present to the public's health and safety. It is provided to the Chair of ICAR in accordance with Executive Order No. 3-52 (No. 04-10).

The Rule Governing the Prescription of Extended Release Hydrocodones Manufactured Without Abuse-Deterrent Formulations was previously filed on April 3, 2014 with an effective date of April 4, 2014. This filing effectively replaces and extends the existing emergency rule that will expire on August 3, 2014. The Department of Health continues to consult with stakeholders for a proposed rule that will address the use of opioids more broadly in be filed in the coming months.

Thank you for your review of this rule. The Department will make itself available for the August 21, 2014 meeting.

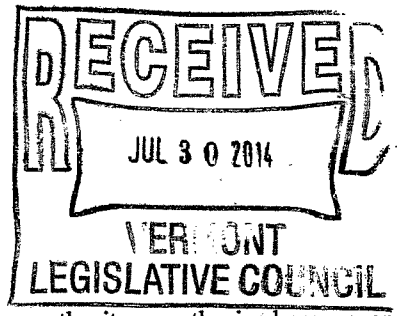
EMERGENCY RULE # 14-E08

Administrative Procedures – Emergency Rule Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" adopted by the Office of the Secretary of State, this emergency filing will be considered complete upon filing of the following components with the Office of the Secretary of State, the Legislative Committee on Administrative Rules and submitting a copy to the Chair of the Interagency Committee on Administrative Rule:

- Emergency Rule Coversheet
- Adopting Page
- Economic Impact Statement
- Public Input Statement
- Scientific Information Statement (if applicable)
- Incorporated by Reference Statement (if applicable)
- Clean text of the rule (Amended text without annotation)
- Annotated text (Clearly marking changes from previous rule)



All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person, and all filings are to be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of the emergency coversheet form will be used to generate a notice of rulemaking in the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency based on the word count of the notices. This emergency rule will be effective for a total of 120 days from the date it takes effect.

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801(b)(11) for a definition), I believe there exists an imminent peril to public health, safety or welfare, requiring the adoption of this emergency rule.

The nature of the peril is as follows (*PLEASE USE ADDITIONAL SHEETS IF SPACE IS INSUFFICIENT*). Due to the imminent peril presented to the public's health and safety by certain drugs that are easily abused, diverted and pose a threat to those who intentionally ingest them, VDH seeks to condition their prescription.

I approve the contents of this filing entitled:

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

DAR for, on 7/28/14.
(signature) (date)

Printed Name and Title:
Douglas A. Racine
Secretary, Agency Of Human Services

RECEIVED BY: _____

- ☐ Emergency Rule Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Statement
- ☐ Public Input Statement
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)

208 HURRICANE LANE, SUITE 103
WILLISTON, VERMONT 05495

OFFICE OF THE SECRETARY
TEL: (802) 871-3009
FAX: (802) 871-3001

DOUGLAS A. RACINE, SECRETARY
DIXIE HENRY, DEPUTY SECRETARY

STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Jim Condos, Secretary of State

FROM: Douglas A. Racine, Secretary

DATE: July 29, 2014

SUBJECT: Signatory for Purposes of Authorizing Administrative Rules

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I hereby designate Deputy Secretary of Human Services Dixie Henry as signatory to fulfill the duties of the Secretary of the Agency of Human Services as the adopting authority for administrative rules as required by Vermont's Administrative Procedure Act, 3 V.S.A. § 801 et seq.

DAR/kp

1. TITLE OF RULE FILING:
   Rule Governing the Prescription of Extended Release Hydrocodones Manufactured Without Abuse-Deterrent Formulations

2. ADOPTING AGENCY:
   Agency of Human Services, Vermont Department of Health (VDH)

3. PRIMARY CONTACT PERSON:
   (A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

   Name: David Englander, Senior Policy And Legal Advisor

   Agency: Vermont Department of Health

   Mailing Address: P.O. Box 70, Burlington, Vt 05402-0070

   Telephone: 802 863 - 7282 ext. Fax: 802 951 - 1275

   E-Mail: david.englander@state.vt.us

   Web URL*(WHERE THE RULE WILL BE POSTED)*:
   http://www.healthvermont.gov/regs/index.aspx

4. SECONDARY CONTACT PERSON:
   (A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

   Name: Bessie Weiss

   Agency: Assistant Attorney General for Vermont Department of Health

   Mailing Address: P.O. Box 70, Burlington, VT 05402-0070

   Telephone: 802 652 - 2092 ext. Fax: 802 951 - 1211

   E-Mail: bessie.weiss@state.vt.us

5. LEGAL AUTHORITY / ENABLING LEGISLATION:
   (THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).
   This rule is adopted pursuant to 3 V.S.A. § 801(b)(11); 18 V.S.A. § 102 and Act No. 75 of the Acts of the 2013 Sess. (2013)

6. CONCISE SUMMARY **(150 WORDS OR LESS)**:

   Extended Release Hydrocodones without abuse-deterrent formulations (ADF) are highly susceptible to abuse, diversion, and potentially lethal to children. Subjecting these drugs to rigorous prescription conditions will minimize the potential for their abuse and diversion and the hazards associated with unintended ingestion.

7. EXPLANATION OF WHY THE RULE IS NECESSARY:

   In order to minimize the potential for abuse, diversion and overdoses of such drugs.

8. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

   Physicians who wish to prescribe hydrocodone without ADFs, patients who might receive them, and the Medical Practice Board.

9. BRIEF SUMMARY OF ECONOMIC IMPACT(**150 WORDS OR LESS**):

   There may be unknown costs saved as a result of low numbers of persons being prescribed these drugs and therefore reduce abuse and overdoses who would otherwise require treatment. There will be a de minimis cost associated with the time needed by prescribers to meet the requirements of the rule to prescribers.

10. A HEARING IS NOT SCHEDULED .

11. HEARING INFORMATION
    (THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

    IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION NEEDED FOR THE NOTICE OF RULEMAKING.

    Date:

    Time: PM

    Location:

    Date:

    Time: PM

    Location:

12. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

13. EMERGENCY RULE EFFECTIVE: 08/04/2014

14. EMERGENCY RULE WILL REMAIN IN EFFECT UNTIL
    (A DATE NO LATER THAN 120 DAYS FOLLOWING ADOPTION OF THIS EMERGENCY RULE):
    12/02/2014

15. NOTICE OF THIS EMERGENCY RULE SHOULD BE PUBLISHED IN THE WEEKLY NOTICES OF RULEMAKING IN THE NEWSPAPERS OF RECORD.

16. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Hydrocodone

Abuse Deterrent Formulation

Zohydro

Run Spell Check

Administrative Procedures – Adopting Page

Instructions:

This form must be completed for each filing made during the rulemaking process:

- Proposed Rule Filing
- Final Proposed Filing
- Adopted Rule Filing
- Emergency Rule Filing

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

1. TITLE OF RULE FILING:
   Rule Governing the Prescription of Extended Release Hydrocodones Manufactured Without Abuse-Deterrent Formulations
2. ADOPTING AGENCY:
   Agency of Human Services, Vermont Department of Health (VDH)
3. AGENCY REFERENCE NUMBER, IF ANY:

4. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

   - **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
   - **NEW RULE** - A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **A NEW RULE** .

5. LAST ADOPTED (*PLEASE PROVIDE THE TITLE AND LAST DATE OF ADOPTION FOR THE EXISTING RULE*):

   Rule Governing the Prescription of Extended Release Hydrocodones Manufactured Without Abuse-Deterrent Formulations, last adopted 4/4/14.

Run Spell Check

Administrative Procedures – Economic Impact Statement

Instructions:

In completing the economic impact statement, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule. This form must be completed for the following filings made during the rulemaking process:

- Proposed Rule Filing
- Final Proposed Filing
- Adopted Rule Filing
- Emergency Rule Filing

Rules affecting or regulating public education and public schools must include cost implications to local school districts and taxpayers in the impact statement (see 3 V.S.A. § 832b for details).

The economic impact statement also contains a section relating to the impact of the rule on greenhouse gases. Agencies are required to explain how the rule has been crafted to reduce the extent to which greenhouse gases are emitted (see 3 V.S.A. § 838(c)(4) for details).

All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person.

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I conclude that this rule is the most appropriate method of achieving the regulatory purpose. In support of this conclusion I have attached all findings required by 3 V.S.A. §§ 832a, 832b, and 838(c) for the filing of the rule entitled:

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

Doug Racine _____, on 7/29/14.
(signature) (date)

Printed Name and Title:
Douglas A. Racine
Secretary, Agency Of Human Services

BE AS SPECIFIC AS POSSIBLE IN THE COMPLETION OF THIS FORM, GIVING FULL INFORMATION ON YOUR ASSUMPTIONS, DATABASES, AND ATTEMPTS TO GATHER OTHER INFORMATION ON THE NATURE OF THE COSTS AND BENEFITS INVOLVED. COSTS AND BENEFITS CAN INCLUDE ANY TANGILBE OR INTANGIBLE ENTITIES OR FORCES WHICH WILL MAKE AN IMPACT ON LIFE WITHOUT THIS RULE.

1. TITLE OF RULE FILING:

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

2. ADOPTING AGENCY:

Agency of Human Services (AHS), Vermont Department of Health (VDH)

3. CATEGORY OF AFFECTED PARTIES:

LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

There may be unknown costs saved as a result of low numbers of persons being prescribed these drugs and therefore reduce abuse and overdoses who would otherwise require treatment. There will be a de minimis cost associated with the time needed by prescribers to meet the requirements of the rule to prescribers.

4. IMPACT ON SCHOOLS:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS:

No effect.

5. COMPARISON:

COMPARE THE ECONOMIC IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

Given the hazards to human health that these substances pose this is a reasonable way to condition the prescription and use of these drugs.

6. FLEXIBILITY STATEMENT:

COMPARE THE BURDEN IMPOSED ON SMALL BUSINESS BY COMPLIANCE WITH THE RULE TO THE BURDEN WHICH WOULD BE IMPOSED BY ALTERNATIVES CONSIDERED IN 3 V.S.A. § 832a:

No effect.

7. GREENHOUSE GAS IMPACT: *EXPLAIN HOW THE RULE WAS CRAFTED TO REDUCE THE EXTENT TO WHICH GREENHOUSE GASES ARE EMITTED, EITHER DIRECTLY OR INDIRECTLY, FROM THE FOLLOWING SECTORS OF ACTIVITIES*:

A. TRANSPORTATION —
IMPACTS BASED ON THE TRANSPORTATION OF PEOPLE OR PRODUCTS (e.g., "THE RULE HAS PROVISIONS FOR CONFERENCE CALLS INSTEAD OF TRAVEL TO MEETINGS" OR "LOCAL PRODUCTS ARE PREFERENTIALLY PURCHASED TO REDUCE SHIPPING DISTANCE."):
No effect.

B. LAND USE AND DEVELOPMENT —
IMPACTS BASED ON LAND USE AND DEVELOPMENT, FORESTRY, AGRICULTURE ETC. (e.g., "THE RULE WILL RESULT IN ENHANCED, HIGHER DENSITY DOWNTOWN DEVELOPMENT." OR "THE RULE MAINTAINS OPEN SPACE, FORESTED LAND AND /OR AGRICULTURAL LAND."):
No effect.

C. BUILDING INFRASTRUCTURE —
IMPACTS BASED ON THE HEATING, COOLING AND ELECTRICITY CONSUMPTION NEEDS (e.g., "THE RULE PROMOTES WEATHERIZATION TO REDUCE BUILDING HEATING AND COOLING DEMANDS." OR "THE PURCHASE AND USE OF EFFICIENT ENERGY STAR APPLIANCES IS REQUIRED TO REDUCE ELECTRICITY CONSUMPTION."):
No effect.

D. WASTE GENERATION / REDUCTION —
IMPACTS BASED ON THE GENERATION OF WASTE OR THE REDUCTION, REUSE, AND RECYCLING OPPORTUNITIES AVAILABLE (e.g., "THE RULE WILL RESULT IN REUSE OF PACKING MATERIALS." OR "AS A RESULT OF THE RULE, FOOD AND OTHER ORGANIC WASTE WILL BE COMPOSTED OR DIVERTED TO A 'METHANE TO ENERGY PROJECT'."):
No effect. There may unknown costs saved as a result of low numbers of persons being prescribed these drugs and therefore reduce abuse and overdoses that would require treatment. There will be a de minimis cost associated with the time needed by prescribers to meet the requirements of the rule to prescribers.

E. OTHER —
IMPACTS BASED ON OTHER CRITERIA NOT PREVIOUSLY LISTED:
None

Run Spell Check

Administrative Procedures – Public Input Statement

Instructions:

In completing the public input statement, an agency describes what it did do, or will do to maximize the involvement of the public in the development of the rule. This form must be completed for the following filings made during the rulemaking process:

- Proposed Rule Filing
- Final Proposed Filing
- Adopted Rule Filing
- Emergency Rule Filing

1. TITLE OF RULE FILING:

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

2. ADOPTING AGENCY:

   Agency of Human Services, Vermont Department of Health (VDH)

3. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

   The Rule has been placed on VDH website.

   http://healthvermont.gov/regs/documents/hydrocodone_emergency_rule.pdf

   In addition, the Department is preparing to file a proposed rule governing the use of opioids in treating chronic pain through normal rule-making process. There will be a public hearing and opportunity for comment from the public and interested parties during that process.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

   The Department reached out to Board of Pharmacy, the Chair of the Vermont Medical Licensing Board, and the Vermont

Medical Society. The Commissioner consulted with the Unified Pain Management System Advisory Council per statutory requirement.

Run Spell Check

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;

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

5.0 Follow-ups and Evaluation

At each follow-up visit required by Section 4.9, 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.

The Vermont Statutes Online

Title 18: Health

Chapter 3: STATE BOARD OF HEALTH

18 V.S.A. § 102. Duties of board

§ 102. Duties of board

The board shall supervise and direct the execution of all laws vested in the department of health by virtue of this title, and shall formulate and carry out all policies relating thereto, and shall make and promulgate such rules and regulations as are necessary to administer this title and shall make a biennial report with recommendations to the governor and to the general assembly. The board may delegate such powers and assign such duties to the commissioner as it may deem appropriate and necessary for the proper execution of provisions of this title. The authority of the board to make and promulgate the rules and regulations shall extend to all matters relating to the preservation of the public health and consistent with the duties and responsibilities of the board. The board's jurisdiction over sewage disposal includes emergent conditions which create a risk to the public health as a result of sewage treatment and disposal, or its effects on water supply, but does not include rulemaking on design standards for on-site sewage disposal systems. (Amended 1959, No. 329 (Adj. Sess.), § 27, eff. March 1, 1961; 1983, No. 117 (Adj. Sess.), § 2.)

Sec. 14a. COMPLEMENTARY AND ALTERNATIVE TREATMENT REPORT

On or before January 15, 2014, the Commissioner of Health shall provide to the House Committees on Human Services and on Health Care and the Senate Committee on Health and Welfare the findings and recommendations of the Unified Pain Management System Advisory Council's initial evaluation of the use of nonpharmacological approaches to treatment for chronic pain, including the use of complementary and alternative therapies. The Commissioner shall provide the Committees with additional recommendations as appropriate as the Advisory Council continues to consider nonpharmacological approaches to treating chronic pain.

Sec. 14b. DEPARTMENT OF HEALTH; ACCESS TO OPIOID TREATMENT

(a) The prevalence of opioid addiction and the lack of sufficient access to opioid treatment in Vermont pose an imminent peril to the public health, welfare, and safety to our citizens.

(b) The Vermont Department of Health shall study how Vermont can increase access to opioid treatment, including methadone and suboxone, by establishing a program whereby state-licensed physicians who are affiliated with a licensed opioid maintenance treatment program may provide methadone or suboxone to opioid-dependent people.

(c) The Commissioner of Health shall consult with the following people:

(1) The Deputy Commissioner of Health for Alcohol and Drug Abuse Programs;

(2) a representative from the Vermont Medical Society;

(3) a representative from the Vermont State Nurses Association;

(4) a representative from the Vermont Board of Medical Practice;

(5) a representative from the Vermont Board of Pharmacy;

(6) a representative from the Vermont Pharmacists Association;

(7) the Commissioner of Public Safety;

(8) a representative of the Vermont Attorney General;

(9) a representative of the Vermont Substance Abuse Treatment Providers Association;

(10) a mental health provider or a certified alcohol and drug abuse counselor;

(11) a consumer in recovery from prescription drug abuse;

(12) a representative from a clinical laboratory providing drug testing and clinical support services to addiction treatment programs;

(13) the Commissioner of Corrections;

(14) The Defender General; and

(15) any other member designated by the Commissioner of Health.

(d)(1) The Department of Health shall adopt rules establishing a program whereby state-licensed physicians who are affiliated with a licensed opioid maintenance treatment program may provide methadone or suboxone to

opioid-dependent people. Such rules may be adopted as emergency rules in accordance with 3 V.S.A. chapter 25. The Department may adopt and enforce such reasonable rules and procedures as are deemed necessary to carry out the administration of the provisions of this section.

(2) The Commissioner of Health shall report its findings, including any recommendations or proposed legislation to the House Committees on Health Care and on Human Services and on Judiciary and Senate Committees on Judiciary and on Health and Welfare on or before January 15, 2014.

Sec. 14c. 33 V.S.A. § 703 is amended to read:

§ 703. ALCOHOL AND DRUG ABUSE COUNCIL; CREATION; TERMS; PER DIEM

(a) The ~~alcohol and drug abuse council~~ Alcohol and Drug Abuse Council is established within the ~~agency of human services~~ Agency of Human Services to promote the reduction of problems arising from alcohol and drug abuse by advising the Secretary on policy areas that can inform agency programs.

(b) The ~~council~~ Council shall consist of ~~eleven~~ 11 members:

(1) the ~~secretary of the agency of human services, commissioner of public safety, commissioner of education, commissioner of liquor control, and commissioner of motor vehicles~~ Secretary of Human Services, Commissioner of Public Safety, Secretary of Education, Commissioner of Liquor Control, and Commissioner of Motor Vehicles or their designees;

VERMONT

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Deadline For Public Comment

Deadline: Unavailable.

The deadline for public comment is unavailable for this rule. Contact the agency or primary contact person listed below for assistance.

Rule Details

Rule Number:	14-E08
Title:	Rule Governing the Prescription of Extended Release Hydrocodones Manufactured Without Abuse-Deterrent Formulations.
Type:	Emergency
Status:	Adopted
Agency:	Department of Health
Legal Authority:	3 V.S.A. § 801(b)(11); 18 V.S.A. § 102 and Act No. 75 of 2013.

Summary:	Extended Release Hydrocodones without abuse-deterrent formulations (ADF) are highly susceptible to abuse, diversion, and potentially lethal to children. Subjecting these drugs to rigorous prescription conditions will minimize the potential for their abuse and diversion and the hazards associated with unintended ingestion.
Persons Affected:	Physicians who wish to prescribe hydrocodone without ADFs, patients who might receive them, and the Medical Practice Board.
Economic Impact:	There may be unknown costs saved as a result of low numbers of persons being prescribed these drugs and therefore reduce abuse and overdoses who would otherwise require treatment. There will be a de minimis cost associated with the time needed by prescribers to meet the requirement of the rule to prescribers.
Posting date:	Aug 04,2014

Hearing Information

There are not Hearings scheduled for this Rule

Contact Information

Information for Contact # 1

Level:	Primary
Name:	David Englander, Senior Policy and Legal Advisor
Agency:	Department of Health
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City:	Burlington
State:	VT
Zip:	05402-0070
Telephone:	802-863-7282
Fax:	802-951-1275
Email:	david.englander@state.vt.us

SEND A COMMENT

Website Address:	http://www.healthvermont.gov/regs/index.aspx VIEW WEBSITE

Information for Contact # 2

Level:	Secondary
Name:	Bessie Weiss, Assistant Attorney General
Agency:	Department of Health
Address:	PO Box 70
City:	Burlington
State:	VT
Zip:	05402-0070
Telephone:	802-652-2092
Fax:	902-951-1211
Email:	bessie.weiss@state.vt.us SEND A COMMENT

Keyword Information

Keywords:

Hydrocodone
Abuse Deterrent Formulation
Zohydro

Back