PROPOSED RULE # _____.

Proposed Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" (CVR 04-000-001) adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms and enclosures with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted to 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 Proposed Filing Coversheet will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Rule Governing the Prescribing of Opioids for Pain

/s/ Todd W. Daloz , on 9/12/23

(signature) (date)

Printed Name and Title:

Todd W. Daloz
Deputy Secretary
Agency of Human Services

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ 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)
- ☐ ICAR Filing Confirmed

1. TITLE OF RULE FILING:
Rule Governing the Prescribing of Opioids for Pain

2. ADOPTING AGENCY:
AHS, Vermont Department of Health

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

Name: Natalie Weill
Agency: AHS, Vermont Department of Health
Mailing Address: 108 Cherry Street, Burlington, VT 05401
Telephone: 802-863-7280 Fax: 8029511275
E-Mail: ahs.vdhrules@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:
http://www.healthvermont.gov/about-us/laws-regulations/public-comment

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: Brendan Atwood
Agency: AHS, Vermont Department of Health
Mailing Address: 108 Cherry Street, Burlington, VT 05401
Telephone: 802-863-7280 Fax: 802-951-1275
E-Mail: ahs.vdhrules@vermont.gov

5. RECORDS EXEMPTION INCLUDED WITHIN RULE:
(DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE, EXEMPTING IT FROM INSPECTION AND COPYING?) No

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

6. 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).
Section 14 (e) of Act 75 (2013); 3 V.S.A § 801(b)(11).

7. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

3 V.S.A. § 801 (b)(11) states, "Adopting authority" means, for agencies that are attached to the Agencies of Administration, of Commerce and Community Development, of Natural Resources, of Human Services, and of Transportation, or any of their components, the secretaries of those agencies; for agencies attached to other departments or any of their components, the commissioners of those departments;…"

Section 14 (e) of Act 75 (2013) states, "The Commissioner of Health may adopt rules pursuant to 3 V.S.A. Chapter 25 regarding the appropriate use of controlled substances…"

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

This rulemaking replaces "naloxone" with "opioid antagonist" to allow for a broader range of medications that can be co-prescribed with opioids when required.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

This amendment provides prescribers the discretion to prescribe the most clinically appropriate opioid antagonist, including potentially lower-cost alternatives to naloxone.

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY AS DEFINED IN 3 V.S.A. § 801(b)(13)(A):

This rulemaking is responsive to the availability of new opioid antagonists alongside naloxone. The decisions made by the Department regarding these regulations are factually based, rationally connected to those factual bases, and would make sense to a reasonable person.

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

Healthcare providers required to co-prescribe an opioid antagonost.

Patients who are prescribed an opioid antagonist.

Medicare, Medicaid and private insurers that are paying for these prescriptions.

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

Lower-cost alternatives to naloxone are expected to be available to patients soon, providing a benefit to patients, Medicaid, Medicare, and insures that are paying for the prescriptions.

13. A HEARING WILL BE SCHEDULED.

IF A HEARING WILL NOT BE SCHEDULED, PLEASE EXPLAIN WHY.

14. 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: 12/19/2023
Time: 01:00 PM
Street Address: 108 Cherry Street, Burlington, VT, Rm 3B
Zip Code: 05401
URL for Virtual: call in (audio only)

+1 802-828-7667,,578834881# United States, Montpelier

Phone Conference ID: 578 834 881#

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:

Time: AM
Street Address:
Zip Code:
URL for Virtual:

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15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING): 12/30/2023
16. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Opioid

nalaxone

opioid antagonist

co-prescribe

Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

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.

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1. TITLE OF RULE FILING:
   Rule Governing the Prescribing of Opioids for Pain
2. ADOPTING AGENCY:
   AHS, Vermont Department of Health
3. 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 if 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 **AN AMENDMENT OF AN EXISTING RULE .**

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):

   Rule Governing the Prescribing of Opioids for Pain, March 1, 2019 Secretary of State Rule Log #19-003

Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

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1. TITLE OF RULE FILING:

   Rule Governing the Prescribing of Opioids for Pain

2. ADOPTING AGENCY:

   AHS, Vermont Department of Health

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:

   Healthcare providers required to co-prescribe an opioid antagonist will have greater discretion when prescribing opioid antagonists.

   Patients who are prescribed an opioid antagonist will have a greater range of medications available to them and may see cost-savings associated with access to lower-cost alternatives to naloxone.

Medicaid, Medicare, and private insurers may also see cost savings associated with access to lower-cost alternatives.

4. IMPACT ON SCHOOLS:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

There are no anticipated impacts to schools.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

Because there are no impacts, alternatives have not been considered.

6. IMPACT ON SMALL BUSINESSES:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

There are no anticipated impacts to small businesses.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

There are no anticipated impacts to small businesses.

8. COMPARISON:
COMPARE THE 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:
This rulemaking allows for potential cost-savings. Without this rulemaking, providers would not be able to co-prescribe potentially lower-cost alternatives to naloxone.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
The Department has provided the relevant information it has based on as assessment of the potential impacts.

Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

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1. TITLE OF RULE FILING:

   Rule Governing the Prescribing of Opioids for Pain

2. ADOPTING AGENCY:

   AHS, Vermont Department of Health

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
   No impact is anticipated.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   No impact is anticipated.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   No impact is anticipated.

6. RECREATION: *EXPLAIN HOW THE RULE IMPACTS RECREATION IN THE STATE:*
   No impact is anticipated.

7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   No impact is anticipated.
8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*
   No impact is anticipated.
9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   The rule does not impact any of the areas listed above, and therefore, this analysis sufficiently captures that there will be no environmental impact.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

This form must accompany each filing made during the rulemaking process:

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1. TITLE OF RULE FILING:

   Rule Governing the Prescribing of Opioids for Pain

2. ADOPTING AGENCY:

   AHS, Vermont Department of Health

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   A public hearing will be held.

   The rule will be posted on the Department of Health website: http://healthvermont.gov/admin/public_comment.aspx.

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

   Vermont Medical Society (VMS)

   Vermont Association of Hospitals and Health Systems (VAHHS)

Rule Governing the Prescribing of Opioids for Pain

1.0 Authority

This rule is adopted pursuant to ~~18 V.S.A. § 4289 (e),~~ Section 14 (e) of Act 75 (2013) ~~and Section 2a of Act 173 (2016)~~.

2.0 Purpose

This rule provides legal requirements for the appropriate use of opioids in treating pain in order to minimize opportunities for misuse, abuse, and diversion, and optimize prevention of addiction and overdose. The prescription limits for acute pain only apply to the first prescription written for a given course of treatment, and do not apply to renewals or refills. This rule only applies to Schedule II, III, or IV Controlled Substances.

3.0 Definitions

3.1 "Abuse" means a maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed. (Federation of State Medical Boards).

3.2 "Abuse-deterrent opioid" means an opioid analgesic medicine determined by the U.S. Food and Drug Administration (FDA) to be expected to result in a meaningful reduction in abuse. These properties may be obtained by: (i) Physical/Chemical barriers that prevent chewing, crushing, cutting, grating, or grinding or chemical barriers that resist extraction using common solvents like water; (ii) Antagonist/Agonist drugs that interfere with, reduce, or defeat the euphoria associated with abuse; (iii) Aversion where substances 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; (iv) Delivery Systems where drug release designs or the method of drug delivery can offer resistance to abuse; (v) Prodrugs where a formulation lacks opioid activity until transformed in the gastrointestinal system; or (vi) a combination of any of the above methods.

3.3 "Administer" or "Administration" means the direct application of a drug by a prescriber to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

3.4 "Acute pain" means pain lasting fewer than 90 days that is a normal and predicted physiological response to a traumatic injury, surgical procedure, or specific disease.

3.5 “Addiction” means a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm or risk of harm. (Federation of State Medical Boards).

3.6 “Assisted living residence” means a program which combines housing, health, and supportive services for the support of resident independence and aging in place. Within a homelike setting, assisted living units offer, at a minimum, a private bedroom, private bath, living space, kitchen capacity, and a lockable door. Assisted living promotes resident self-direction and active participation in decision-making while emphasizing individuality, privacy, and dignity. Defined in 33 V.S.A. §7102(1).

3.7 “Chronic Pain" means pain caused by various diseases or abnormal conditions and that continues longer than 90 consecutive days.

3.8 “Controlled Substance” means a drug, other substance, or immediate precursor, included in Schedules II, III, or IV of the federal Controlled Substances Act (CSA).

3.9 “Controlled Substance Treatment Agreement” means a document that is signed and agreed upon by both the prescriber and the patient, acknowledging the rights and responsibilities of being on and prescribing controlled substances, and the treatment expectations.

3.10 “Diversion” means the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution including, but not limited to, the sharing or purchasing of drugs between family and friends or individual theft from family and friends. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances.

3.11 “Functional Examination” means an examination used to describe an individual’s ability to perform key daily activities and to evaluate changes in the activities of everyday life. It encompasses physical, social, and psychological domains, and covers outcomes from baseline functions through death.

3.12 “Hospice Care” means a program of care and support provided by a Medicare-certified hospice provider to help an individual with a terminal condition to live comfortably by providing palliative care, including effective pain and symptom management. Hospice care may include services provided by an interdisciplinary team that are intended to address the physical, emotional, psychosocial, and spiritual needs of the individual and his or her family. As defined in 18 V.S.A. 9710(b)

3.13 “Hospice-eligible” means a person who is terminally ill and qualifies to receive hospice services but is not enrolled in a hospice program.

3.14 "High-Risk" means a patient at increased risk for misuse, abuse, diversion, addiction, overdose, or other aberrant behaviors as determined by the patient's history and/or the risk assessment tool chosen by the provider.

3.15 "MME" means Morphine Milligram Equivalent. The use of MME allows prescribers to equate the dosage of opioid in a given medication. e.g. compare oxycodone with hydromorphone. A MME calculator can be found on the Department of Health website.

3.16 "Misuse" means the use of a medication (with therapeutic intent) other than as directed or as indicated whether willful or unintentional, and whether harm results or not.

3.17 "Nursing home", means an institution or distinct part of an institution which is primarily engaged in providing to its residents any of the following:

3.17.1 skilled nursing care and related services for residents who require medical or nursing care;

3.17.2 rehabilitation services for the rehabilitation of persons who are injured, have a disability, or are sick;

3.17.3 on a 24-hour basis, health-related care and services to individuals who, because of their mental or physical condition, require care, and services which can be made available to them only through institutional care.
Defined in 33 V.S.A. §7102(7).

3.18 "OTP" means an Opioid Treatment Program as defined and regulated by federal regulation 42 CFR, Part 8 and DEA regulations related to safe storage and dispensing of OTP's (1301.72). OTP's are specialty addiction treatment programs for dispensing opioid-replacement medication including methadone and buprenorphine under carefully controlled and observed conditions. In Vermont, OTP's are sometimes referred to as "Hubs."

3.19 "Opioid naïve" means a patient who has not used opioids for more than seven consecutive days during the previous 30 days.

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

3.21 "Prescribe" means an order for medication that is dispensed to or for an ultimate user but does not include an order for medication that is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

3.22 "Residential care home" means a place, however named, excluding a licensed foster home, which provides, for profit or otherwise, room, board, and personal care to three or more residents unrelated to the home operator. Residential care homes shall be divided into two groups, depending upon the level of care they provide, as follows:

3.22.1 Level III, which provides personal care, defined as assistance with meals, dressing, movement, bathing, grooming, or other personal needs, or general supervision of physical or mental well-being, including nursing overview and medication management as defined by the licensing agency by rule, but not full-time nursing care; and

3.22.2 Level IV, which provides personal care, as described in subdivision (A) of this subdivision (10), or general supervision of the physical or mental well-being of residents, including medication management as defined by the licensing agency by rule, but not other nursing care.
Defined in 33 V.S.A. §7102(10).

3.23 "Risk Assessment" means a process for predicting a patient's likelihood of misusing or abusing opioids in order to develop and document a level of monitoring for that patient. An example of a screening tool is the Screener and Opioid Assessment for Patients with Pain (SOAPP), but prescribers can use any evidence-based screening tool.

4.0 Universal Precautions when Prescribing Opioids for Pain

Prior to writing a prescription for an opioid Schedule II, III, or IV Controlled Substance for the first time during a course of treatment to any patient, providers shall adhere to the following universal precautions, unless otherwise exempt by this rule.

4.1 Consider Non-Opioid and Non-Pharmacological Treatment

Prescribers shall consider non-opioid and non-pharmacological treatments for pain management and include any appropriate treatments in the patient's medical record. Such treatments may include, but are not limited to:

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Acetaminophen
- Acupuncture
- Osteopathic manipulative treatment
- Chiropractic
- Physical therapy

4.2 Query the Vermont Prescription Monitoring System according to the Vermont Prescription Monitoring System Rule.

4.3 Provide Patient Education and Informed Consent

4.3.1 **Discussion of Risks**: Prior to prescribing an opioid, a prescriber shall have an in-person discussion with the patient regarding potential side effects, risks of dependence and overdose, alternative treatments, appropriate tapering and safe storage and disposal. If the patient is a minor, or lacks legal competence, then the in-person discussion shall take place between the prescriber and the patient's parent, guardian, or legal representative, unless otherwise provided for by law.

4.3.2 **Patient Education Sheet**: Prior to prescribing an opioid, the prescriber shall provide the patient with the Department of Health patient education sheet published on the Department website, or a written alternative provided that the sheet contains all of the topics found in the Department-published sheet and is written in a fifth-grade reading level or lower.

4.3.3 **Informed Consent**: Prior to prescribing an opioid, a prescriber shall receive a signed informed consent from the patient. If the patient is a minor or lacks the capacity to provide informed consent, then the patient's parent, guardian, or legal representative may do so on the patient's behalf, unless otherwise provided for by law.

4.3.3.1 The consent form shall include: Information regarding the drug's potential for misuse, abuse, diversion, and addiction; potential side effects; tolerance; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and potentially fatal overdose when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates.

5.0 Prescribing Opioids for Acute Pain

5.1 The purpose of this section is to provide prescribers with a framework for prescribing opioids in the smallest doses for the shortest periods of time to be effective in the management of pain.

5.1.1 The limits found in Figures 1.0 and 2.0 are maximums, not therapeutic recommendations.

5.1.2 The daily maximums found in Figure 1.0 and 2.0 are averages, not absolute daily limits. The average daily limit may allow larger doses at the start of the prescription with smaller doses at the end as the patient tapers.

5.2 The following limits apply to patients who are opioid naïve and are receiving their first prescriptions not administered in a healthcare setting.

5.3 These limits do not prohibit a provider from writing a second prescription (or renewal/refill prescription) for the patient should that be necessary.

5.4 The framework provides four categories, each with its own limits, shown in Figure 1.0 for adults ages 18 years old and older and Figure 2.0 for children ages 0-17 years old. The pain category into which a patient is placed is based on the medical judgment of the prescriber.

5.4.1 For adults ages 18 years old and older, should a provider prescribe an average daily dose over 32 morphine milligram equivalents, the reason must be justified in the medical record.

Figure 1.0 – Opioid Limits for Adults Ages 18 Years Old or Older

Pain	Average Daily MME *(allowing for tapering)*	Prescription TOTAL MME based on expected duration of pain	Common average DAILY pill counts	Commonly associated injuries, conditions and surgeries
Minor pain	No Opioids	0 total MME	0 hydrocodone 0 oxycodone 0 hydromorphone	molar removal, sprains, non-specific low back pain, headaches, fibromyalgia, un-diagnosed dental pain
Moderate pain	24 MME/day	0-3 days: **72 MME** 1-5 days: **120 MME**	4 hydrocodone 5mg or 3 oxycodone 5mg or 3 hydromorphone 2mg	non-compound bone fractures, most soft tissue surgeries, most outpatient laparoscopic surgeries, shoulder arthroscopy
Severe pain	32 MME/day	0-3 days: **96 MME** 1-5 days: **160 MME**	6 hydrocodone 5mg or 4 oxycodone 5mg or 4 hydromorphone 2mg	many non-laparoscopic surgeries, maxillofacial surgery, total joint replacement, compound fracture repair
For patients with severe pain and extreme circumstance, the provider can make a clinical judgement to prescribe up to 7 days so long as the reason is documented in the medical record.				
Extreme Pain	50 MME/day	7 day MAX: 350 MME	10 hydrocodone 5mg or 6 oxycodone 5mg or 6 hydromorphone 2mg	similar to the severe pain category but with complications or other special circumstances

Figure 2.0 – Opioid Limits for Children Ages 0-17 Years

Pain	Average Daily MME *(allowing for tapering)*	Prescription TOTAL MME based on expected duration of pain	Common average DAILY pill counts	Commonly associated injuries, conditions and surgeries
Minor pain	No Opioids	0 total MME	0 hydrocodone 0 oxycodone 0 hydromorphone	molar removal, sprains, non-specific low back pain, headaches, fibromyalgia, un-diagnosed dental pain
Moderate to **Severe** pain	24 MME/day	0-3 days: **72 MME**	4 hydrocodone 5mg or 3 oxycodone 5mg or 3 hydromorphone 2mg	non-compound bone fractures, most soft tissue surgeries, most outpatient laparoscopic surgeries, shoulder arthroscopy

5.5 Extended-release/Long-acting Opioids

Long-acting opioids are not indicated for acute pain. Should a provider need to use a long-acting opioid for acute pain for a specific reason, that reason must be justified in the patient's medical record.

5.6 Consultation and Transfer of Patient Care

5.6.1 While treating an adult patient for acute pain, and prior to ending a patient's care for acute pain, a prescriber who is not the patient's primary care provider shall ensure a safe transition of care by making a reasonable effort to communicate with the patient's primary care provider with any relevant clinical information concerning the patient's condition, diagnosis and treatment. A clear discharge summary that includes expectations for ongoing pain treatment shall satisfy this requirement.

5.6.2 Prior to prescribing an opioid to a child in an Emergency Department, Urgent Care setting or specialty care setting, prescribers shall make a reasonable effort to consult with that child's primary care provider.

5.7 Exemptions

The following conditions, and those similar to them in the medical judgment of the healthcare provider, are exempt from the limits found in section 5.4:

- Pain associated with significant or severe trauma
- Pain associated with complex surgical interventions, such as spinal surgery

- Pain associated with prolonged inpatient care due to post-operative complications
- Medication-assisted treatment for substance use disorders
- Patients who are not opioid naïve
- Other circumstances as determined by the Commissioner of Health

6.0 Prescribing Opioids for Chronic Pain

The following section outlines requirements for prescribing Schedule II, III or IV opioids for chronic pain (pain lasting longer than 90 days). If the provider is prescribing to the patient for the first time during a course of treatment, the Universal Precautions in Section 4.0 also apply. The requirements in this section apply to patients who are receiving an opioid for the treatment of chronic pain.

6.1 Screening, Evaluation, and Risk Assessment

6.1.1 The prescriber shall conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record when prescribing opioids for chronic pain.

6.1.2 The prescriber shall document in the patient's medical record any diagnoses which support the use of opioids for relief of chronic pain.

6.1.3 The prescriber shall evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient of the use of opioids prior to writing an opioid prescription for chronic pain. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.0 of this rule.

6.1.4 Examples of risk assessment screening tools are available on the Department of Health website.

6.2 Initiating an Opioid Prescription for Chronic Pain

6.2.1 Prior to prescribing an opioid for the treatment of chronic pain, the prescriber shall consider and document in the patient's medical record:

6.2.1.1 Non-opioid alternatives up to a maximum recommended by the FDA, including non-pharmacological treatments, have been considered;

6.2.1.2 Trial use of the opioid;

6.2.1.3 Any applicable requirements to query the Vermont Prescription Monitoring System;

6.2.1.4 That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone or buprenorphine or prescribed and taken any other controlled substance. The prescriber shall explain that this information is important for the patient's safety and that the patient is required by law to disclose this information (18 V.S.A.§4223);

6.2.1.5 Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, and safe storage and disposal of medication. It shall include other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance.

6.2.2 For the duration of the patient's treatment of chronic pain with opioids, the provider shall:

6.2.2.1 Schedule and undertake periodic follow-up visits and evaluations at a frequency determined by the patient's risk factors, the medication dose and other clinical indictors. Patients who are stable in terms of the medication dose and its effectiveness in managing chronic pain must be reevaluated no less than once every 90 days; and

6.2.2.2 Write the maximum daily dose or a "not to exceed" equivalent on the prescription for the dispensing pharmacy.

6.2.2.3 Examples of informed consent documents and Controlled Substance Treatment Agreements shall be made available on the Department of Health's website.

6.3 Referrals and Consultations

The prescriber shall consider referring a patient for a consultation with an appropriate specialist (such as a pain specialist or substance abuse specialist) when:

6.3.1 The patient is not meeting the goals of treatment despite escalating doses of controlled substances for pain;

6.3.2 The patient is at high-risk for substance misuse, abuse, diversion, addiction, or overdose as determined by the patient's history or a screening undertaken pursuant to Section 1 of this rule;

6.3.3 The prescriber has reasonable grounds to believe, or confirms, a patient is misusing opioids or other substances;

6.3.4 The patient is seeing multiple prescribers and/or utilizing multiple pharmacies;

6.3.5 The patient has been prescribed multiple controlled substances; or

6.3.6 The patient requests a referral.

6.4 Reevaluation of Treatment

6.4.1 Controlled Substance Treatment Agreements for people receiving treatment for chronic pain shall be reviewed by the prescriber and patient no less frequently than once every 365 days to reevaluate the patient. These reviews shall be documented in the patient's medical record.

6.4.2 Prior to prescribing a dose of opioids, or a combination of opioids, that exceeds a Morphine Milligram Equivalent Daily Dose of 90 the prescriber shall document in the patient's medical record:

6.4.2.1 A reevaluation of the effectiveness and safety of the patient's pain management plan, including an assessment of the patient's adherence to the treatment regimen;

6.4.2.2 The potential for the use of non-opioid and non-pharmacological alternatives for treating pain;

6.4.2.3 A functional examination of the patient;

6.4.2.4 A review of the patient's Controlled Substance Treatment Agreement and Informed Consent, making any necessary revisions, including pill counts and directly observed urine testing to monitor adherence and possible use of other substances;

6.4.2.5 An assessment of any co-morbid conditions affected by treatment with opioids. This may be best conducted by a mental health or addictions professional; and

6.4.2.6 Any other related actions by the patient that may reasonably lead a prescriber to modify the pain management regimen, including but not limited to aberrant behaviors, early refills of controlled substances, or other known risks associated with misuse, abuse, diversion, addiction, or overdose.

6.4.2.7 Prior to prescribing a patient an average Morphine Milligram Equivalent Daily Dose of 90 or more, a prescriber shall have an

in-person discussion with the patient, regarding the increased risk of fatal and non-fatal overdose, and any precautions the patient should take. If the patient is a minor, or lacks legal competence, then this in-person discussion shall take place between the prescriber and the patient's parent, guardian, or legal representative, unless otherwise provided for by law.

6.4.3 Based on the reevaluation the prescriber shall determine and document:

6.4.3.1 Whether to continue the treatment of pain with opioids or if there are available alternatives;

6.4.3.2 The possible need for a pain management, substance abuse or pharmacological consultation to achieve effective pain management, avoidance of dependence or addiction or taper from the prescribed analgesics; and

6.4.3.3 Acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription. This may occur after consultation with an addiction~~s~~ specialist.

6.5 Exemptions

Patients experiencing chronic pain in the following categories are exempt from the requirements found in this section:

- Chronic pain associated with cancer or cancer treatment
- Patients in nursing homes

7.0 Co-Prescription of ~~Naloxone~~ Opioid Antagonist

7.1 Prescribers shall co-prescribe an FDA-approved opioid antagonist (e.g. naloxone) or document in the medical record that a patient has a valid prescription for, or states they are in possession of, an opioid antagonist ~~naloxone~~ for:

7.1.1 All patients who receive one or more opioid prescriptions totaling a Morphine Milligram Equivalent Daily Dose of 90 or more.

7.1.2 All patients receiving a prescription that results in concurrent use of an opioid and benzodiazepines.

7.2 In cases where there is more than one prescriber involved in the patient's care, the prescriber responsible for meeting the requirements of 7.1 is the prescriber writing the prescription triggering either 7.1.1 or 7.1.2.

8.0 Prescription of Extended Release Hydrocodones and Oxycodones without Abuse Deterrent Opioid Formulations

Whereas, extended release hydrocodones and oxycodones that are not manufactured as Abuse-deterrent Opioids are easily misused, abused, diverted, and pose an increased threat to those who unintentionally ingest them, this rule requires specific conditions for their prescription that are in addition to provisions of Sections 4.0 through 7.0 of this rule.

8.1 Prior to prescribing an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid, the prescriber shall:

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

8.1.2 Document in the patient's medical record any diagnoses which support the use of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid for pain relief;

8.1.3 Evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient of the use of extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid prior to writing a prescription for such a substance. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.0 of this rule;

8.1.4 Document in the patient's medical record that the prescription of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid 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 are otherwise inadequate to provide sufficient management of pain;

8.1.5 Receive, and include in the patient's medical record a signed Informed Consent from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative, that shall include information regarding the drug's potential for misuse, abuse, diversion, and addiction; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and potentially fatal overdose when combining with alcohol;

8.1.6 Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient, or if the patient lacks the capacity, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, safe storage and disposal of medication, and urine testing (no less frequently than annually with the actual frequency to

be determined by the clinician on the basis of the patient's risk assessment and ongoing behavior). It shall include other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance;

8.1.7 Query VPMS and document it in the patient's medical record. The prescriber shall also document in the patient's medical record:

8.1.7.1 A review of other controlled substances prescribed to the patient prior to the first prescription of an extended-release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid;

8.1.7.2 A query no less frequently than once every 120 days for any patient prescribed 40 mg or greater of hydrocodone or 30 mg or greater of oxycodone per day of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid as long as the patient possesses a valid prescription for that amount; and

8.1.7.3 A query no less frequently than as described in the Vermont Prescription Monitoring System rule.

8.1.8 Determine and write a maximum daily dose, or a "not to exceed value" for the prescription to be transmitted; and

8.1.9 Write a prescription that must be filled within seven (7) days of the date issued and does not exceed a 30-day supply.

8.2 Prescribers subject to this section shall schedule and undertake periodic follow-up visits and evaluations (no less frequently than every 90 days), during which the following must be documented in the patient's medical record:

8.2.1 Whether to continue the treatment of pain with an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid or if there are available alternatives;

8.2.2 The possible need for a pain management or substance abuse consultation; and

8.2.3 A provider explanation and a patient acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription. This may occur after consultation with an addiction~~s~~ specialist.

9.0 Prescribing Opioids for Hospice, and Hospice-eligible Patients

9.1 Patients who are terminally ill, receiving hospice services or who are hospice-eligible are exempt from Sections 4 – 7 of this rule.

9.2 Prescribers shall comply with the following concerning patient education:

9.2.1 **Safe Storage and Disposal:** prior to prescribing an opioid, a prescriber shall inform the patient regarding safe storage and disposal for patients receiving an opioid outside of a health care setting. If the patient is a minor, or lacks legal competence, the patient shall inform the patient's parent, guardian, or legal representative, unless otherwise provided for by law.

9.2.2 **Patient Education Sheet:** prior to prescribing an opioid, a prescriber shall provide the patient with the Department of Health patient education sheet published on the Department of Health website, or a written alternative provided that the sheet contains all the topics found in the Department-published sheet and is written in a fifth-grade reading level or lower.

Rule Governing the Prescribing of Opioids for Pain

1.0 Authority

This rule is adopted pursuant to Section 14 (e) of Act 75 (2013).

2.0 Purpose

This rule provides legal requirements for the appropriate use of opioids in treating pain in order to minimize opportunities for misuse, abuse, and diversion, and optimize prevention of addiction and overdose. The prescription limits for acute pain only apply to the first prescription written for a given course of treatment, and do not apply to renewals or refills. This rule only applies to Schedule II, III, or IV Controlled Substances.

3.0 Definitions

3.1 "Abuse" means a maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed. (Federation of State Medical Boards).

3.2 "Abuse-deterrent opioid" means an opioid analgesic medicine determined by the U.S. Food and Drug Administration (FDA) to be expected to result in a meaningful reduction in abuse. These properties may be obtained by: (i) Physical/Chemical barriers that prevent chewing, crushing, cutting, grating, or grinding or chemical barriers that resist extraction using common solvents like water; (ii) Antagonist/Agonist drugs that interfere with, reduce, or defeat the euphoria associated with abuse; (iii) Aversion where substances 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; (iv) Delivery Systems where drug release designs or the method of drug delivery can offer resistance to abuse; (v) Prodrugs where a formulation lacks opioid activity until transformed in the gastrointestinal system; or (vi) a combination of any of the above methods.

3.3 "Administer" or "Administration" means the direct application of a drug by a prescriber to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

3.4 "Acute pain" means pain lasting fewer than 90 days that is a normal and predicted physiological response to a traumatic injury, surgical procedure, or specific disease.

3.5 “Addiction” means a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm or risk of harm. (Federation of State Medical Boards).

3.6 “Assisted living residence” means a program which combines housing, health, and supportive services for the support of resident independence and aging in place. Within a homelike setting, assisted living units offer, at a minimum, a private bedroom, private bath, living space, kitchen capacity, and a lockable door. Assisted living promotes resident self-direction and active participation in decision-making while emphasizing individuality, privacy, and dignity. Defined in 33 V.S.A. §7102(1).

3.7 “Chronic Pain" means pain caused by various diseases or abnormal conditions and that continues longer than 90 consecutive days.

3.8 “Controlled Substance” means a drug, other substance, or immediate precursor, included in Schedules II, III, or IV of the federal Controlled Substances Act (CSA).

3.9 “Controlled Substance Treatment Agreement” means a document that is signed and agreed upon by both the prescriber and the patient, acknowledging the rights and responsibilities of being on and prescribing controlled substances, and the treatment expectations.

3.10 “Diversion” means the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution including, but not limited to, the sharing or purchasing of drugs between family and friends or individual theft from family and friends. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances.

3.11 “Functional Examination” means an examination used to describe an individual’s ability to perform key daily activities and to evaluate changes in the activities of everyday life. It encompasses physical, social, and psychological domains, and covers outcomes from baseline functions through death.

3.12 “Hospice Care” means a program of care and support provided by a Medicare-certified hospice provider to help an individual with a terminal condition to live comfortably by providing palliative care, including effective pain and symptom management. Hospice care may include services provided by an interdisciplinary team that are intended to address the physical, emotional, psychosocial, and spiritual needs of the individual and his or her family. As defined in 18 V.S.A. 9710(b)

3.13 “Hospice-eligible” means a person who is terminally ill and qualifies to receive hospice services but is not enrolled in a hospice program.

3.14 "High-Risk" means a patient at increased risk for misuse, abuse, diversion, addiction, overdose, or other aberrant behaviors as determined by the patient's history and/or the risk assessment tool chosen by the provider.

3.15 "MME" means Morphine Milligram Equivalent. The use of MME allows prescribers to equate the dosage of opioid in a given medication. e.g. compare oxycodone with hydromorphone. A MME calculator can be found on the Department of Health website.

3.16 "Misuse" means the use of a medication (with therapeutic intent) other than as directed or as indicated whether willful or unintentional, and whether harm results or not.

3.17 "Nursing home", means an institution or distinct part of an institution which is primarily engaged in providing to its residents any of the following:

3.17.1 skilled nursing care and related services for residents who require medical or nursing care;

3.17.2 rehabilitation services for the rehabilitation of persons who are injured, have a disability, or are sick;

3.17.3 on a 24-hour basis, health-related care and services to individuals who, because of their mental or physical condition, require care, and services which can be made available to them only through institutional care.
Defined in 33 V.S.A. §7102(7).

3.18 "OTP" means an Opioid Treatment Program as defined and regulated by federal regulation 42 CFR, Part 8 and DEA regulations related to safe storage and dispensing of OTP's (1301.72). OTP's are specialty addiction treatment programs for dispensing opioid-replacement medication including methadone and buprenorphine under carefully controlled and observed conditions. In Vermont, OTP's are sometimes referred to as "Hubs."

3.19 "Opioid naïve" means a patient who has not used opioids for more than seven consecutive days during the previous 30 days.

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

3.21 "Prescribe" means an order for medication that is dispensed to or for an ultimate user but does not include an order for medication that is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

3.22 "Residential care home" means a place, however named, excluding a licensed foster home, which provides, for profit or otherwise, room, board, and personal care to three or more residents unrelated to the home operator. Residential care homes shall be divided into two groups, depending upon the level of care they provide, as follows:

3.22.1 Level III, which provides personal care, defined as assistance with meals, dressing, movement, bathing, grooming, or other personal needs, or general supervision of physical or mental well-being, including nursing overview and medication management as defined by the licensing agency by rule, but not full-time nursing care; and

3.22.2 Level IV, which provides personal care, as described in subdivision (A) of this subdivision (10), or general supervision of the physical or mental well-being of residents, including medication management as defined by the licensing agency by rule, but not other nursing care.
Defined in 33 V.S.A. §7102(10).

3.23 "Risk Assessment" means a process for predicting a patient's likelihood of misusing or abusing opioids in order to develop and document a level of monitoring for that patient. An example of a screening tool is the Screener and Opioid Assessment for Patients with Pain (SOAPP), but prescribers can use any evidence-based screening tool.

4.0 Universal Precautions when Prescribing Opioids for Pain

Prior to writing a prescription for an opioid Schedule II, III, or IV Controlled Substance for the first time during a course of treatment to any patient, providers shall adhere to the following universal precautions, unless otherwise exempt by this rule.

4.1 Consider Non-Opioid and Non-Pharmacological Treatment

Prescribers shall consider non-opioid and non-pharmacological treatments for pain management and include any appropriate treatments in the patient's medical record. Such treatments may include, but are not limited to:

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Acetaminophen
- Acupuncture
- Osteopathic manipulative treatment
- Chiropractic
- Physical therapy

4.2 Query the Vermont Prescription Monitoring System according to the Vermont Prescription Monitoring System Rule.

4.3 Provide Patient Education and Informed Consent

4.3.1 **Discussion of Risks**: Prior to prescribing an opioid, a prescriber shall have an in-person discussion with the patient regarding potential side effects, risks of dependence and overdose, alternative treatments, appropriate tapering and safe storage and disposal. If the patient is a minor, or lacks legal competence, then the in-person discussion shall take place between the prescriber and the patient's parent, guardian, or legal representative, unless otherwise provided for by law.

4.3.2 **Patient Education Sheet**: Prior to prescribing an opioid, the prescriber shall provide the patient with the Department of Health patient education sheet published on the Department website, or a written alternative provided that the sheet contains all of the topics found in the Department-published sheet and is written in a fifth-grade reading level or lower.

4.3.3 **Informed Consent**: Prior to prescribing an opioid, a prescriber shall receive a signed informed consent from the patient. If the patient is a minor or lacks the capacity to provide informed consent, then the patient's parent, guardian, or legal representative may do so on the patient's behalf, unless otherwise provided for by law.

4.3.3.1 The consent form shall include: Information regarding the drug's potential for misuse, abuse, diversion, and addiction; potential side effects; tolerance; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and potentially fatal overdose when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates.

5.0 Prescribing Opioids for Acute Pain

5.1 The purpose of this section is to provide prescribers with a framework for prescribing opioids in the smallest doses for the shortest periods of time to be effective in the management of pain.

5.1.1 The limits found in Figures 1.0 and 2.0 are maximums, not therapeutic recommendations.

5.1.2 The daily maximums found in Figure 1.0 and 2.0 are averages, not absolute daily limits. The average daily limit may allow larger doses at the start of the prescription with smaller doses at the end as the patient tapers.

5.2 The following limits apply to patients who are opioid naïve and are receiving their first prescriptions not administered in a healthcare setting.

5.3 These limits do not prohibit a provider from writing a second prescription (or renewal/refill prescription) for the patient should that be necessary.

5.4 The framework provides four categories, each with its own limits, shown in Figure 1.0 for adults ages 18 years old and older and Figure 2.0 for children ages 0-17 years old. The pain category into which a patient is placed is based on the medical judgment of the prescriber.

5.4.1 For adults ages 18 years old and older, should a provider prescribe an average daily dose over 32 morphine milligram equivalents, the reason must be justified in the medical record.

Figure 1.0 – Opioid Limits for Adults Ages 18 Years Old or Older

Pain	Average Daily MME *(allowing for tapering)*	Prescription TOTAL MME based on expected duration of pain	Common average DAILY pill counts	Commonly associated injuries, conditions and surgeries
Minor pain	No Opioids	0 total MME	0 hydrocodone 0 oxycodone 0 hydromorphone	molar removal, sprains, non-specific low back pain, headaches, fibromyalgia, un-diagnosed dental pain
Moderate pain	24 MME/day	0-3 days: **72 MME** 1-5 days: **120 MME**	4 hydrocodone 5mg or 3 oxycodone 5mg or 3 hydromorphone 2mg	non-compound bone fractures, most soft tissue surgeries, most outpatient laparoscopic surgeries, shoulder arthroscopy
Severe pain	32 MME/day	0-3 days: **96 MME** 1-5 days: **160 MME**	6 hydrocodone 5mg or 4 oxycodone 5mg or 4 hydromorphone 2mg	many non-laparoscopic surgeries, maxillofacial surgery, total joint replacement, compound fracture repair
For patients with severe pain and extreme circumstance, the provider can make a clinical judgement to prescribe up to 7 days so long as the reason is documented in the medical record.				
Extreme Pain	50 MME/day	7 day MAX: 350 MME	10 hydrocodone 5mg or 6 oxycodone 5mg or 6 hydromorphone 2mg	similar to the severe pain category but with complications or other special circumstances

Figure 2.0 – Opioid Limits for Children Ages 0-17 Years

Pain	Average Daily MME *(allowing for tapering)*	Prescription TOTAL MME based on expected duration of pain	Common average DAILY pill counts	Commonly associated injuries, conditions and surgeries
Minor pain	No Opioids	0 total MME	0 hydrocodone 0 oxycodone 0 hydromorphone	molar removal, sprains, non-specific low back pain, headaches, fibromyalgia, un-diagnosed dental pain
Moderate to **Severe** pain	24 MME/day	0-3 days: **72 MME**	4 hydrocodone 5mg or 3 oxycodone 5mg or 3 hydromorphone 2mg	non-compound bone fractures, most soft tissue surgeries, most outpatient laparoscopic surgeries, shoulder arthroscopy

5.5 Extended-release/Long-acting Opioids

Long-acting opioids are not indicated for acute pain. Should a provider need to use a long-acting opioid for acute pain for a specific reason, that reason must be justified in the patient's medical record.

5.6 Consultation and Transfer of Patient Care

5.6.1 While treating an adult patient for acute pain, and prior to ending a patient's care for acute pain, a prescriber who is not the patient's primary care provider shall ensure a safe transition of care by making a reasonable effort to communicate with the patient's primary care provider with any relevant clinical information concerning the patient's condition, diagnosis and treatment. A clear discharge summary that includes expectations for ongoing pain treatment shall satisfy this requirement.

5.6.2 Prior to prescribing an opioid to a child in an Emergency Department, Urgent Care setting or specialty care setting, prescribers shall make a reasonable effort to consult with that child's primary care provider.

5.7 Exemptions

The following conditions, and those similar to them in the medical judgment of the healthcare provider, are exempt from the limits found in section 5.4:

- Pain associated with significant or severe trauma
- Pain associated with complex surgical interventions, such as spinal surgery

- Pain associated with prolonged inpatient care due to post-operative complications
- Medication-assisted treatment for substance use disorders
- Patients who are not opioid naïve
- Other circumstances as determined by the Commissioner of Health

6.0 Prescribing Opioids for Chronic Pain

The following section outlines requirements for prescribing Schedule II, III or IV opioids for chronic pain (pain lasting longer than 90 days). If the provider is prescribing to the patient for the first time during a course of treatment, the Universal Precautions in Section 4.0 also apply. The requirements in this section apply to patients who are receiving an opioid for the treatment of chronic pain.

6.1 Screening, Evaluation, and Risk Assessment

6.1.1 The prescriber shall conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record when prescribing opioids for chronic pain.

6.1.2 The prescriber shall document in the patient's medical record any diagnoses which support the use of opioids for relief of chronic pain.

6.1.3 The prescriber shall evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient of the use of opioids prior to writing an opioid prescription for chronic pain. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.0 of this rule.

6.1.4 Examples of risk assessment screening tools are available on the Department of Health website.

6.2 Initiating an Opioid Prescription for Chronic Pain

6.2.1 Prior to prescribing an opioid for the treatment of chronic pain, the prescriber shall consider and document in the patient's medical record:

6.2.1.1 Non-opioid alternatives up to a maximum recommended by the FDA, including non-pharmacological treatments, have been considered;

6.2.1.2 Trial use of the opioid;

6.2.1.3 Any applicable requirements to query the Vermont Prescription Monitoring System;

6.2.1.4 That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone or buprenorphine or prescribed and taken any other controlled substance. The prescriber shall explain that this information is important for the patient's safety and that the patient is required by law to disclose this information (18 V.S.A.§4223);

6.2.1.5 Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, and safe storage and disposal of medication. It shall include other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance.

6.2.2 For the duration of the patient's treatment of chronic pain with opioids, the provider shall:

6.2.2.1 Schedule and undertake periodic follow-up visits and evaluations at a frequency determined by the patient's risk factors, the medication dose and other clinical indictors. Patients who are stable in terms of the medication dose and its effectiveness in managing chronic pain must be reevaluated no less than once every 90 days; and

6.2.2.2 Write the maximum daily dose or a "not to exceed" equivalent on the prescription for the dispensing pharmacy.

6.2.2.3 Examples of informed consent documents and Controlled Substance Treatment Agreements shall be made available on the Department of Health's website.

6.3 Referrals and Consultations

The prescriber shall consider referring a patient for a consultation with an appropriate specialist (such as a pain specialist or substance abuse specialist) when:

6.3.1 The patient is not meeting the goals of treatment despite escalating doses of controlled substances for pain;

6.3.2 The patient is at high-risk for substance misuse, abuse, diversion, addiction, or overdose as determined by the patient's history or a screening undertaken pursuant to Section 1 of this rule;

6.3.3 The prescriber has reasonable grounds to believe, or confirms, a patient is misusing opioids or other substances;

6.3.4 The patient is seeing multiple prescribers and/or utilizing multiple pharmacies;

6.3.5 The patient has been prescribed multiple controlled substances; or

6.3.6 The patient requests a referral.

6.4 Reevaluation of Treatment

6.4.1 Controlled Substance Treatment Agreements for people receiving treatment for chronic pain shall be reviewed by the prescriber and patient no less frequently than once every 365 days to reevaluate the patient. These reviews shall be documented in the patient's medical record.

6.4.2 Prior to prescribing a dose of opioids, or a combination of opioids, that exceeds a Morphine Milligram Equivalent Daily Dose of 90 the prescriber shall document in the patient's medical record:

6.4.2.1 A reevaluation of the effectiveness and safety of the patient's pain management plan, including an assessment of the patient's adherence to the treatment regimen;

6.4.2.2 The potential for the use of non-opioid and non-pharmacological alternatives for treating pain;

6.4.2.3 A functional examination of the patient;

6.4.2.4 A review of the patient's Controlled Substance Treatment Agreement and Informed Consent, making any necessary revisions, including pill counts and directly observed urine testing to monitor adherence and possible use of other substances;

6.4.2.5 An assessment of any co-morbid conditions affected by treatment with opioids. This may be best conducted by a mental health or addictions professional; and

6.4.2.6 Any other related actions by the patient that may reasonably lead a prescriber to modify the pain management regimen, including but not limited to aberrant behaviors, early refills of controlled substances, or other known risks associated with misuse, abuse, diversion, addiction, or overdose.

6.4.2.7 Prior to prescribing a patient an average Morphine Milligram Equivalent Daily Dose of 90 or more, a prescriber shall have an

in-person discussion with the patient, regarding the increased risk of fatal and non-fatal overdose, and any precautions the patient should take. If the patient is a minor, or lacks legal competence, then this in-person discussion shall take place between the prescriber and the patient's parent, guardian, or legal representative, unless otherwise provided for by law.

6.4.3 Based on the reevaluation the prescriber shall determine and document:

6.4.3.1 Whether to continue the treatment of pain with opioids or if there are available alternatives;

6.4.3.2 The possible need for a pain management, substance abuse or pharmacological consultation to achieve effective pain management, avoidance of dependence or addiction or taper from the prescribed analgesics; and

6.4.3.3 Acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription. This may occur after consultation with an addictions specialist.

6.5 Exemptions

Patients experiencing chronic pain in the following categories are exempt from the requirements found in this section:

- Chronic pain associated with cancer or cancer treatment
- Patients in nursing homes

7.0 Co-Prescription of Opioid Antagonist

7.1 Prescribers shall co-prescribe an FDA-approved opioid antagonist (e.g. naloxone) or document in the medical record that a patient has a valid prescription for, or states they are in possession of, an opioid antagonist for:

7.1.1 All patients who receive one or more opioid prescriptions totaling a Morphine Milligram Equivalent Daily Dose of 90 or more.

7.1.2 All patients receiving a prescription that results in concurrent use of an opioid and benzodiazepines.

7.2 In cases where there is more than one prescriber involved in the patient's care, the prescriber responsible for meeting the requirements of 7.1 is the prescriber writing the prescription triggering either 7.1.1 or 7.1.2.

8.0 Prescription of Extended Release Hydrocodones and Oxycodones without Abuse Deterrent Opioid Formulations

Whereas, extended release hydrocodones and oxycodones that are not manufactured as Abuse-deterrent Opioids are easily misused, abused, diverted, and pose an increased threat to those who unintentionally ingest them, this rule requires specific conditions for their prescription that are in addition to provisions of Sections 4.0 through 7.0 of this rule.

8.1 Prior to prescribing an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid, the prescriber shall:

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

8.1.2 Document in the patient's medical record any diagnoses which support the use of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid for pain relief;

8.1.3 Evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient of the use of extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid prior to writing a prescription for such a substance. The evaluation shall include but not be limited to a Risk Assessment as defined in Section 3.0 of this rule;

8.1.4 Document in the patient's medical record that the prescription of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid 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 are otherwise inadequate to provide sufficient management of pain;

8.1.5 Receive, and include in the patient's medical record a signed Informed Consent from the patient, or, if the patient lacks the capacity to provide informed consent, from the patient's legal representative, that shall include information regarding the drug's potential for misuse, abuse, diversion, and addiction; the risks associated with the drug for life-threatening respiratory depression; potentially fatal overdose as a result of accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and potentially fatal overdose when combining with alcohol;

8.1.6 Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient, or if the patient lacks the capacity, from the patient's legal representative. This agreement must include functional goals for treatment, dispensing pharmacy choice, safe storage and disposal of medication, and urine testing (no less frequently than annually with the actual frequency to

be determined by the clinician on the basis of the patient's risk assessment and ongoing behavior). It shall include other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance;

8.1.7 Query VPMS and document it in the patient's medical record. The prescriber shall also document in the patient's medical record:

8.1.7.1 A review of other controlled substances prescribed to the patient prior to the first prescription of an extended-release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid;

8.1.7.2 A query no less frequently than once every 120 days for any patient prescribed 40 mg or greater of hydrocodone or 30 mg or greater of oxycodone per day of an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid as long as the patient possesses a valid prescription for that amount; and

8.1.7.3 A query no less frequently than as described in the Vermont Prescription Monitoring System rule.

8.1.8 Determine and write a maximum daily dose, or a "not to exceed value" for the prescription to be transmitted; and

8.1.9 Write a prescription that must be filled within seven (7) days of the date issued and does not exceed a 30-day supply.

8.2 Prescribers subject to this section shall schedule and undertake periodic follow-up visits and evaluations (no less frequently than every 90 days), during which the following must be documented in the patient's medical record:

8.2.1 Whether to continue the treatment of pain with an extended release hydrocodone or oxycodone that is not an Abuse-deterrent Opioid or if there are available alternatives;

8.2.2 The possible need for a pain management or substance abuse consultation; and

8.2.3 A provider explanation and a patient acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription. This may occur after consultation with an addiction specialist.

9.0 Prescribing Opioids for Hospice, and Hospice-eligible Patients

9.1 Patients who are terminally ill, receiving hospice services or who are hospice-eligible are exempt from Sections 4 – 7 of this rule.

9.2 Prescribers shall comply with the following concerning patient education:

9.2.1 **Safe Storage and Disposal:** prior to prescribing an opioid, a prescriber shall inform the patient regarding safe storage and disposal for patients receiving an opioid outside of a health care setting. If the patient is a minor, or lacks legal competence, the patient shall inform the patient's parent, guardian, or legal representative, unless otherwise provided for by law.

9.2.2 **Patient Education Sheet:** prior to prescribing an opioid, a prescriber shall provide the patient with the Department of Health patient education sheet published on the Department of Health website, or a written alternative provided that the sheet contains all the topics found in the Department-published sheet and is written in a fifth-grade reading level or lower.

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JENNEY SAMUELSON
SECRETARY

TODD W. DALOZ
DEPUTY SECRETARY

STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Sarah Copeland Hanzas, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services

DATE: January 31, 2023

SUBJECT: Signatory Authority for Purposes of Authorizing Administrative Rules

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I hereby designate Deputy Secretary of Human Services Todd W. Daloz 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.

Cc: Todd W. Daloz