Vermont Medical Society Comments
APPENDIX B: Draft Amendments

VDH Rule Governing the Prescribing of Opioids for Pain

Sections 1.0-3.0 - No change except "provider" to "prescriber" in 3.10

4.0 Universal Precautions when Prescribing Opioids for Pain

Except when exempt under section 8.0, prior to ~~writing a prescription~~ prescribing an opioid Schedule II, III or IV Controlled Substance for the first time to any patient, ~~providers~~ prescribers shall adhere to the following universal precautions.

4.1 Consider Non-opioid and Non-Pharmacological Treatment

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

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Acetaminophen
- Acupuncture
- Chiropractor or
- Physical therapy

4.2 Query the Vermont Prescription Monitoring System

Prescribers must query the Vermont Prescription Monitoring program in compliance with the Vermont Department of Health Rule Chapter 8, Subchapter 7, Vermont Prescription Monitoring System Rule.

4.3 Provide Patient Education and Informed Consent

~~4.3.1 Discussion of Risks~~ [section deleted, merged with below]

4.3.1 ~~4.3.2~~ **Patient Education and Informed Consent Form ~~Sheet~~:** ~~Prior to prescribing an opioid~~ [section 4.0 already defines when this sub-section applies] A prescriber or designee shall provide the patient with the Department of Health patient education and informed consent form published on the Health Department website and provide the patient, guardian, health care agent or other legal representative with an opportunity to ask questions. The form may be provided in an electronic format.

4.3.1.1 ~~4.3.2.1~~ The Health Department education and consent form shall include: Information regarding the drug's potential for misuse, abuse, diversion, and addiction; potential side effects, including 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; alternative treatments; appropriate tapering; and safe storage and disposal of controlled substances.

4.3.1.2 The Department shall review the education and consent form on an annual basis.

4.3.2 **Documentation:** The prescriber or designee shall document in the medical record that the patient was provided the patient education and consent form and had an opportunity to ask questions.

4.3.3. **Exemption**: This Section shall not apply in emergency situations.

4.3.3 **Effective Date:** This section shall take effect after the Vermont Department of Health has published the patient information sheet.

~~4.3.3 Informed Consent~~ [section deleted, merged with above]

4.4 Co-prescription of Naloxone [no change, though see comments]

5.0 Prescribing Opioids for Acute Pain

~~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.~~ [Moved Below]

5.1 ~~Maximum~~ Morphine Milligram Equivalent~~s~~ Guidelines

The purpose of this section is to provide prescribers with ~~a framework~~ guidelines for prescribing opioids in the smallest doses for the shortest periods of time to be effective in the management of pain. The ~~framework~~ guidelines provide~~s~~ ~~four~~ three categories. The category into which a patient is placed is based on the medical judgment of the prescriber and can take into account factors such as the expected level of patient pain due to the severity of the injury, condition or procedure; the patient's subjective experience of pain; and objective indices of the patient's pain. Prescribers should document the prescriber's assessment of pain that justifies the prescription. ~~Doses higher than those described in this section may be exceeded consistent with Section 5.4 but must be justified in the medical record.~~

Opioids should generally be avoided in the treatment of pain associated with conditions for which evidence shows that non-opioid alternatives are as effective or are more effective than opioids. These include but are not limited to: sprains, ~~non-specific low back pain~~ [evidence re: lack of efficacy applies to chronic pain not acute], ~~headaches~~ [evidence re: lack of efficacy applies to chronic headaches; acute headaches may be due to trauma, etc], fibromyalgia, un-diagnosed dental pain, periodontal surgery, minor dental procedures and tooth extraction.

[Strike remainder of matrix, as drafted, Sections 5.1.1-5.2.3.2]

5.1.1 Mild Pain

If the patient is experiencing or expected to experience mild levels of pain, prescribers should consider limiting individual prescriptions to:

- Total prescription of 72 Morphine Milligram Equivalents (72 MME/Rx)
- 24 Morphine Milligram Equivalent Daily Dose
- A PRN or as-needed basis for up to 3 days.

5.1.2 Moderate Pain

If the patient is experiencing or expected to experience moderate levels of pain, prescribers should consider limiting individual prescriptions to:

- Total prescription of 72-120 Morphine Milligram Equivalents (72-120 MME/Rx)
- 24 Morphine Milligram Equivalent Daily Dose
- Up to 5 days.

5.1.3 Severe Pain

If the patient is experiencing or expected to experience severe levels of pain, prescribers should consider limiting individual prescriptions to:

- Total prescription of 96-160 Morphine Milligram Equivalents (96-160 MME/Rx)
- 32 Morphine Milligram Equivalent Daily Dose
- Up to 7 days.

The Department shall reassess these guidelines on an annual basis to ensure they reflect current medical evidence and best clinical practice.

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5.4 2 Maximum Prescribing of Opioids for Acute Pain [Note that proposed rule was missing sections 5.2 and 5.3]

5.2.1 Adults

Except as provided in Sub-Section 5.2.4, ~~providers shall~~ individual prescriptions for opioid Schedule II, III or IV Controlled substances written for acute pain for those 18 and older shall not exceed a:

- Total ~~prescription~~ of 350 Morphine Milligram Equivalents;
- 50 Morphine Milligram Equivalent Daily Dose; and
- Total of no more than 7 days.

5.2.2 Minors [moved from section 7.0; consultation in 7.1 overlaps with new 6.5; limits for minor procedures in 7.2 overlaps with new section 6.3]

Except as provided in Sub-Section 5.2.4, individual prescriptions for opioid Schedule II, III or IV Controlled substances written for acute pain for those under 18 shall not exceed a:

- Total ~~prescription~~ of 72 Morphine Milligram Equivalents ~~of 72~~;
- 24 Morphine Milligram Equivalent Daily Dose ~~of 24~~; and
- Total of ~~0 3 days~~ no more than 3 days.

5.2.3 Refills

Nothing in this subsection precludes a prescriber's ability to provide refills of medications consistent with the limitations in this subsection.

5.2.4 ~~9.2~~ Exemptions

A ~~prescriber~~ prescription is exempt from the limits ~~on opioid medication prescribing~~ established in Section 5.~~0~~2 of this rule ~~only~~ when ~~prescribing~~ prescribed for:

- Pain associated ~~multi-system~~ significant or severe trauma
- Pain associated with major or c~~C~~omplex surgical interventions ~~such as spinal surgery~~
- Post-operative pain following discharge from an ~~Persons released from an~~ in-patient care setting ~~necessitated by post-operative complications~~
- Medication-assisted treatment for substance use disorder
- Patients who have used opioids in the past thirty (30) days ~~are not opiate naïve~~

The basis for an exemption must be ~~documented~~ contained in the medical record.

5.~~5~~ ~~3~~ Extended-release/Long-acting Opioids

Typically, long-acting opioids are not indicated for acute pain. Should a ~~provider~~ prescriber 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~~ 4 Transfer of Patient Care

Prior to ending a patient's care for pain, a prescriber shall ~~ensure a safe transition of care by~~ make~~ing~~ a reasonable effort to contact the patient's primary care provider with any relevant clinical information concerning the patient's condition, diagnosis and treatment. This may include sending a paper or electronic copy of a discharge note or relevant portion of a patient record.

6.0 Prescribing Opioid for Chronic Pain

[No specific amendments proposed, though see comments regarding consistency between this section and section on universal precautions.]

~~**7.0 Prescribing Opioids to Minors**~~ - [Removed and incorporated into Section 5, above]

~~8~~ 7.0 Prescription of Extended Release Hydrocodones and Oxycodones without Abuse Deterrent Opioid Formulations – no change except "provider" to "prescriber" in Section 8.2.3

~~9~~ 8.0 Exemptions

~~9.1~~ A prescriber is exempt from ~~the limits on opioid medication prescribing established in the~~ this rule ~~only~~ when prescribing for:

- Pain associated with active and aftercare cancer treatment
- Palliative care
- End of life and hospice care
- Patients in skilled and intermediate care nursing facilities
- Administration to a patient in a health care facility licensed by the Department
- Other circumstances as determined by the Commissioner of Health

~~9.2~~ [Exemptions from Section 5.0 – moved to section 5]

~~9.3 Any exemption must be documented in the medical record.~~

VDH Vermont Prescription Monitoring System Rule

Section 1.0 Authority – no change

Section 2.0 Purpose – Remove last sentence: "The use of VPMS in treating chronic paint due to cancer, hospice care, and other end-of-life care is not required" as exemptions clarified and moved to proposed sub-section 6.4

Sections 3.0 Definitions – 3.2, "Chronic Pain," – remove "but is not caused by cancer or end-state terminal disease."

Sections 4.0– 5.0 – no change

Section 6.0 Requirements for Prescribers

Section 6.2.2: remove "non-palliative" as palliative care exemption moved to proposed sub-section 6.4

6.4 Exemptions [new proposal]

A prescriber is exempt from the requirements to query the VPMS prior to prescribing a controlled substance in the following circumstances:

- When prescribing for pain associated with active and aftercare cancer treatment; palliative care or end of life and hospice care;
- When prescribing for patients in skilled and intermediate care nursing facilities;
- When administering medication to a patient in a health care facility licensed by the Department;
- When treating acute pain post-operatively for no more than 7 days or;
- When treating acute pain associated with traumatic injury or acute medical condition, with clear objective findings by the prescriber, from an Emergency Department or Urgent Care prescriber for no more than 7 days;
- If it is not reasonably possible for the prescriber to access the registry in a timely manner due to electronic or technological failure or temporary lack of access and the amount prescribed is for no more than 7 days; and [exemption consistent w. Act 173]
- Other circumstances as determined by the Commissioner of Health.

Section 7.0 Access to VPMS Information - no changes proposed, see comments for questions regarding VDH-proposed removal of sections

Section 8.0 Protection, Disclosure and Use of VPMS Information

8.1 Disclosing Information from the VPMS

8.1.1 – no changes

8.1.2 The Department shall report to each prescriber on an annual basis a summary of the prescriber's controlled substance prescribing including, but not limited to:

8.1.2.1 Patient-level reports that include: patient names and identifiers and prescription details and dates for the year

8.1.2.2 A summary report that may include: the number of patients receiving acute or chronic controlled substance prescriptions and patients receiving high risk prescriptions such as high dose prescriptions or opioids prescribed concurrently with benzodiazepines.

~~8.1.2 –~~ renumber to 8.1.3

8.2 Coordination of VPMS Information

Within three years of the effective date of these rules, the Department shall ensure that the VPMS system has the functionality to integrate with all Electronic Medical Records systems used by prescribers in the State.

Sections 9.0 & 10.0 – no changes