VERMONT MEDICAL SOCIETY

Date: October 27. 2016

To: Lillian Colasurdo, Vermont Department of Health, via email to: *AHS.VDHRules@vermont.gov*

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CC: Harry Chen, MD, Commissioner, Vermont Department of Health; David Englander, Senior Policy and Legal Advisor, Vermont Department of Health; Vermont Medical Society Council; VMS Opioid Task Force

Re: **Vermont Medical Society Comments**
Proposed Rule - Rule Governing the Prescribing of Opioids for Pain
Proposed Rule - Vermont Prescription Monitoring System Rule

Thank you for the opportunity to present comments from Vermont Medical Society (VMS) members regarding the Department of Health's Proposed Rule Governing the Prescribing of Opioids for Pain and Proposed Vermont Prescription Monitoring System Rule.

The VMS is the state's largest physician membership organization, representing over 2000 physicians, medical residents and medical students across specialties and geographic location. Responsible opioid use is a top priority for our members. VMS recognizes that more can be done to ensure that opioid prescribing is guided by high quality medical evidence with regard to efficacy and safety for individual patients and for society at large. We support efforts to ensure that prescribing is appropriate and consistent with available evidence and that an oversupply of opioids, addiction and overdoses are prevented. At the same time, limits to opioids must be balanced against ensuring that patients with legitimate acute and chronic pain are able to receive adequate, legal pain control. We look forward to partnering with the Vermont Department of Health (VDH) to help our State and these rules strike the appropriate balance for the patients of Vermont between a need for pain control and preventing addiction or other harm.

VMS has distributed the draft rules and drafts of amendments and comments to our full membership as well as our leadership council and multi-disciplinary Opioid Task Force. We have held a conference call to solicit input as well as collected individual phone calls and written responses. Overall, we have heard from over two dozen clinicians, including our physician-members, but also nurse practitioners, pharmacists, and other practitioners. See Appendix A for a full list of clinicians providing input to VMS.

Below is a summary of the feedback we have received and VMS' concerns and recommendations regarding the VDH-proposed rules. **VMS' concerns fall into three categories: (1) concerns regarding the lack of an evidence-base for the rules (2) concerns regarding the feasibility of implementing the rules based on lack of clarity of language, counterintuitive structure of the rule, and the number of steps, processes and analyses required of prescribers; and (3) process concerns**. Please also see Appendix B for draft amendments to the rules, addressing many of these concerns. Note that the structure and section numbers found in these comments reflect the Department's proposed rules and the VMS draft amendments renumber and structure certain sections to increase the ability of prescribers to understand and implement the requirements.

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1. **Lack of Evidence-Basis for the Rules**

VMS fully supports responsible opioid prescribing, consistent with available evidence. The VMS Council has endorsed a policy resolution – to be submitted to the full VMS membership on November 5th - stating that: *"The Vermont Medical Society will endeavor to change the paradigm of using opioids for chronic non-malignant pain so that such use is guided by high quality medical evidence with regard to efficacy and safety both for individual patients and for society at large."* Consistent with this policy, VMS supports guidelines for prescribing that are based in medical evidence.

Our members have commented that there no medical or scientific evidence supporting the following aspects of the proposed Rule Governing the Prescribing of Opioids for Pain:

- A seven-day cap on prescriptions of opioids for acute pain (Section 5.4). In fact, all of the surgeons responding noted that there are types of procedures, for example, shoulder arthroscopy and other "bony" orthopedic procedures when more than 7 days of opioids are commonly required. Early data from a study being conducted at the University of Vermont Medical Center to determine if patients have been prescribed the appropriate amount of analgesic medicine following a range of surgical procedures show that 40% of patients following hip replacement are still taking opioids 5-7 days after their surgery. In recognition of the need to allow clinical judgement, Massachusetts law, while also containing a 7-day cap, states that: if "in the professional medical judgment of a practitioner, more than a 7-day supply of an opiate is required to treat the adult or minor patient's acute medical condition. . . then the practitioner may issue a prescription for the quantity needed to treat such acute medical condition."[1]
- The matrix established in Section 5.1/Figure 1, creating limits on prescribing based on the intensity or complexity of conditions or procedures. None of our members were familiar with evidence supporting the specific definitions of conditions or dosages of medication and days stated. Rushing the implementation detailed limits undermines significant work that practices and facilities across the state are engaging in to develop protocols and tools to address appropriate opiate prescribing, such as the study UVM-MC is conducting, mentioned above. Full results from that study are expected in November.
- A restriction on acute opioid prescriptions for headaches (Section 5.1.1). Evidence suggests that opioids are not effective for chronic headaches but acute needs for opioids could arise for a number of reasons, such as a headache following trauma.
- A restriction on acute opioid prescriptions for low back pain (Section 5.1.1). Evidence suggests that opioids are not effective for chronic, non-specific low back pain but leaves open the question of efficacy for acute needs and would depend on the reason for the acute pain.
- The limits on prescribing for minors established in Section 7.3: Total MME of 72, MME DD of 24, Total of 0-3 days. In contrast, Massachusetts law contains a 7-day cap for minors with exceptions for if "in the professional medical judgment of a practitioner, more than a 7-day supply of an opiate is required to treat the . . . minor patient's acute medical condition."[2]
- Checking VPMS for every new, acute prescription (Section 4.2; also see Proposed Vermont Prescription Monitoring System Rule Section 6.2.1). While some members, especially those in

[1] Mass. Law Chapter 52 – Acts of 2016, Section 24(b)
[2] *Id.*

primary care, responded with support for a universal requirement for checking the VPMS, the majority responded that there is no evidence to support that this requirement will reduce harm or have benefits for patients, especially when prescribing for pain post-operatively when a prescriber would likely prescribe opioids regardless of what the VPMS yields.

VMS Recommendations:

Rather than relying on one-size-fits all caps, the Department of Health should develop specialty-specific rules that establish temporal or dose prescribing guidelines based on research and clinical best practice - and that allow some level of flexibility in individual patient cases. An example can be found in the Consensus Statement created by the Emergency Room directors across Vermont recommending best practices for prescribing opioids in the acute care setting. Thanks to efforts like these, Prescription Monitoring System data shows that the number of opioid prescriptions began decreasing in 2015.

The VDH should include in rules or otherwise make publically available the evidence basis for any temporal or dose prescribing limits or guidelines. If evidence or research is lacking, the VDH should wait for available evidence before establishing arbitrary limits. For example, the VDH should incorporate the findings expected in November of the post-surgical opioid use research being conducted by UVM-MC to ensure that guidelines for prescribing are appropriate for a range of specialties or procedures and are consistent with best clinical practice.

If VDH decides to move forward with limits and/or a prescribing matrix, VMS has included in our amendments a number of suggestions to make the rules more consistent with clinical practice and allow for the clinical judgment of prescribers. For example, the Section 5.1 Maximum Morphine Equivalents and the "framework" for prescribing should clearly state that these are only guidelines and not binding requirements, leaving room for clinical judgement. This section should also focus on the level of pain the patient is experiencing, rather than the severity of the procedure. VMS heard universally from our members that patients respond to procedures differently and that prescribers base their prescribing decisions primarily on the expected or actual pain of the patient rather than the intensity of procedure. VMS has proposed amendments that keep the overall temporal and dose guidelines established in the VDH draft but reframes it in terms of the patient's pain, as determined by the expected level of pain due to the severity of the injury or procedure; the patient's subjective experience of pain; and objective indices of the patient's pain. The Department should reexamine these guidelines on an annual basis to ensure they reflect current medical evidence and best clinical practice.

These changes are also consistent with Act 173 that not only directed the Department to consider rules on prescribing but directed "each professional licensing authority for health care providers [to] develop evidence-based standards to guide health care providers" in appropriately prescribing opioids for acute and chronic pain – the Department should not be overly-prescriptive, leaving room for the licensing authorities to develop additional appropriate evidence-based standards.

2. Feasibility of Implementation

The VMS is very concerned with the feasibility of implementing this rule. Our concerns stem from the lack of clarity in the language in many sections of the rule, as well as from the number of additional administrative requirements that the rule places on prescribers writing acute opioid prescriptions.

As an example of how the rule may impact a physician prescribing for an acute need, consider the ten steps, processes and analysis that would be required for just one short-term prescription of an opioid for a patient - for example, a patient who presents in the emergency department with a broken bone for which the physician thinks sort-term prescription of an opioid is appropriate:[3]

1. Consider non-opioid/non-pharmacological treatments (Section 4.1)
2. Document appropriate non-opioid treatments in the medical record (Section 4.1)
3. Query the Vermont Prescription Monitoring System (Section 4.2)
4. Have an in-person discussion regarding potential side effects of opioids (Section 4.3.1)
5. Provide the patient with an education form (Section 4.3.2)
6. Provide and receive a signed informed consent form (Section 4.3.3)
7. Decide whether the injury is defined as "minor" or "moderate" (Section 5.1.1 or 5.2.1)
8. If prescribing more than 3 days/dose higher than that contained in matrix based on the severity of the condition, but less than overall caps found in Section 5.4, document the decision in the medical record (Section 5.1)
9. Prior to discharge, make a "reasonable effort" to contact the patient's primary care provider (Section 5.6)
10. Consider and document any other special circumstances that may apply, such as a co-prescribing of naloxone (Section 4.4), whether this is a minor (in which case, different prescribing limits and requirements to consult with PCP apply) (Section 7.0), or if an exemption to limits apply (for example, if the patient received other opioids within past 30 days) (Section 9.2)

Rather than attempt to comply and risk running afoul of the regulations and face disciplinary sanctions, this level of regulatory detail will lead to non-ideal outcomes for the patients of Vermont such as prescribers simply refusing to prescribe opiates, or surgeons referring all post-operative pain control to primary care clinicians.

There are also many areas in the rule that lack clarity, making implementation an additional struggle. For example, it is unclear when the exemptions apply to the rule; whether the morphine milligram equivalent "framework" is binding or suggested; and how the section on minors relates to the overall prescribing limits and exemptions.

[3] Compare these ten requirements to Massachusetts (requiring documentation in the record of the need for the prescription and consideration of non-opioid alternatives only if prescribing for *more than* 7 days) and New Hampshire (for acute prescriptions only requiring documentation of the rational for the prescription and providing the patient with an information form). Mass Law Chapter 52 – Acts of 2016, Section 24(b); New Hampshire's Rule Med 502.05.

In more detail, VMS' concerns regarding interpretation and understanding of rule and suggestions for improvement are as follows (see also Appendix B for suggested language):

Rule Governing the Prescribing of Opioids for Pain

1. **Section 4.0**, Universal Precautions: It is unclear whether the exemptions found in Section 9.1 - when prescribing for pain associated with cancer treatment, palliative care, end-of-life, hospice care and patients in nursing facilities - apply to the universal precautions in Section 4.0. Currently, Section 9.1 only states that in the exempt cases prescribers are "exempt from the limits on opioid medication prescribing" without any reference to specific sections of the rule. Therefore, Section 4.0 requirements of considering non-opioid alternatives, checking VPMS, and providing education and consent may apply in all situations.

   There is also an overall inconsistency in the rule between using the term "provider" (found in this section 4.0 as well as the section 3.10, "high risk" definition; 5.1.1.2; 5.4, 5.5; and 8.2.3) and using the term "prescriber" (remainder of rule).

   VMS Recommendations: Prescribing for cancer treatment, palliative care, end-of-life and hospice care should be exempt from all requirements of the rule to minimize barriers to appropriate pain management in these situations. Section 4.0 should clearly state that this section does not apply if an overall exemption applies (those found in VDH proposed rule section 9.1). Ideally, Section 9.1 would also be moved within the rule to above Section 4.0 – providing an easier-to-understand structure for prescribers that these exemptions apply to the entire rule. As described further below, section 9.1 should also be amended to state that the exemptions apply to the entire rule.

   References to "provider" in this section and others mentioned above should be amended to "prescriber."

2. **Section 4.1**, Consider non-opioid alternatives: As written, this section appears to require considering and documenting all non-opioid or non-pharmacological treatments, whether or not applicable to the patient's situation.

   VMS Recommendation: Clarify that the prescriber must only consider appropriate/ applicable alternatives and document those actually recommended in the patient record.

3. **Section 4.2**: Query the VPMS

   This section lacks clarity regarding how it relates to the Vermont Prescription Monitoring System rule – for example, would exemptions for cancer or hospice care apply.

   VMS Recommendation: To minimize confusion and inconsistency, this section should simply cross-reference a requirement to comply with the VPMS system rule.

4. **Section 4.3,** Provide Patient Education and Informed consent: It is unclear if the three-step process of discussion of risks, providing a patient education form and obtaining a signed, informed consent form created in this section is expected to occur even in emergency/trauma situations, whether a designee can assist with this process and how this process would proceed in a busy emergency or urgent-care setting. Further, the three

requirements for a discussion of risks, a patient education form and signed informed consent form are duplicative and burdensome and not required under Act 173. While "informed consent" is required by Act 173, as understood in the medical-legal context informed consent does not need to be a written, signed document. Signed informed consent is not required in any other prescription context and could impede patient access to care. For example, if the patient refuses to sign the form is the prescriber required to deny a prescription even if desired by the patient? In addition, any discrepancy between an education form developed by the Department and an informed consent form developed by a prescriber or facility would increase patient confusion.

VMS Recommendations: This process should be simplified to allow for implementation by prescribers and ensure that it is meaningful to patients. The Department should develop one integrated education and informed consent form. To obtain informed consent, the prescriber or designee should provide this form to the patient, use the form as the basis for a discussion and provide an opportunity for a patient or legal representative to ask questions. The prescriber or designee should document this discussion in the medical record. VMS also supports Rutland Regional Medical Center's recommendation that this section contain an emergency exemption. The Department should review the form annually to ensure that the information provided in the form is still accurate and reflects current information regarding risks and benefits of opioids.

5. **Section 4.4**, Co-prescribing of naloxone: It is unclear how to implement the co-prescribing requirement as all of section 4.0 is limited to when a prescriber writes a first-time opioid prescription. Our members questioned whether this is the only time co-prescribing would be required.

   VMS Recommendation: Clarify when co-prescribing is required and consider moving to a different section of the rule that is not limited to first-time prescriptions.

6. **Section 5.0 (5.1-5.4),** Prescribing Opioids for Acute Pain: In addition to the concerns discussed above, regarding a lack of evidence base, this section of the rule proved very concerning to our members due to difficulty with both interpreting and administering the requirements. VMS members stated that it was very unclear whether or which elements of Section 5.1 were indeed binding or only providing guidance. To begin, Section 5.0 states that this section provides a "framework" for prescribing and the doses "may be exceeded consistent with Section 5.4." Yet, the subsections on "minor," "moderate" and "major" conditions are drafted with mandatory language, stating that prescribers "shall not" exceed certain doses or timeframes of medication (See sections 5.2.1.1, 5.2.1.2, 5.2.3.1 and 5.2.3.2). As another example, 5.1.1.1 states that "opioids shall be avoided" for minor injuries then immediately after in 5.1.1.2 states that "should a provider need to use an opioid" they must document the reason. And, the exemptions in Section 9.2 state that they apply to the "limits on opioid medication prescribing established in Section 5.0 of the rule" when it may be the intent that only Section 5.4 provides a binding limit. Further, our members responded that the definitions of "minor," "moderate" or "major" were not clear or helpful. For example, what is the difference between a "undergoing a complex

procedure" including "total joint replacement" in Section 5.2.3 and a "complex surgical intervention" exempt from the limits by section 9.2.

Members were further concerned about the time and level of analysis required to walk through the matrix for every prescription written. It would require first categorizing a procedure based on severity, then analyzing the level of pain the individual was experiencing, then looking to the overall cap in Section 5.4, then an exemption in Section 9.2.

VMS Recommendations: While not changing the overall limits and guidelines, this section should be significantly simplified and clarified, with suggested language provided in Appendix B. First, the prescribing "framework" found in Section 5.1 should state clearly that it provides guidelines rather than binding limits. These guidelines should be stated in terms of the prescriber's assessment of the level of patient pain requiring treatment rather than the type of procedure. This is more consistent with how prescribers approach prescribing opioids and allows the framework to be simplified and collapsed into fewer categories. To minimize confusion between how to apply the framework and prescribing limits found in Section 5.4, the upper limit suggested for addressing "severe" pain should be consistent, at 7 days. The list of conditions for which opioids should be avoided should be modified to be consistent with current evidence by removing nonspecific low back pain and headaches, as lack of evidence applies to chronic prescriptions for these conditions and not acute.

Next, the overall limits for prescribing for both adults (Section 5.4) and children (Section 7.3) should be stated clearly in one place. (Note that ideally, the overall limits for prescribing for both adults and children and exemptions to those limits should be stated before the Section 5.1 guidelines in order to create a more understandable flow of the rule for prescribers trying to interpret the requirements).

This section should clarify to prescribers that refills, consistent with the limits of this rule and any other legal requirements, are not precluded. As currently drafted, the limits in Section 5.4 and 7.3 apply to "providers," rather than to "prescriptions," so that the limit of 7 days (or 3 days for minors) could prevent a prescriber from ever providing a refill. The language should be amended to apply to an individual prescription, and explicit language allowing refills should be added.

Finally, in order to simplify implementation, the exemptions to the prescribing limits (section 9.2) should be moved to this section. VMS also proposes several amendments to the Section 9.2 exemptions reflecting questions received from our members. For example: the exemption should reference the firm prescribing caps (Section 5.02) rather than the entire section 5.0, which includes the "framework" that should already be non-binding so not require exemptions; pain following "major or complex" surgical interventions should be exempt, to reflect that these terms are interchangeable and it would not be possible to operationalize a difference between "major" and "complex" procedures; and pain from "significant or severe" trauma should be exempt not requiring the arbitrary need for a trauma to be "multi-system." VMS also recommends that, to avoid unnecessary documentation, an exemption need not be explicitly reflected in the medical record as an

exemption, but that the medical record must reflect the basis for the exemption (for example, that the patient experienced severe trauma).

7. **Section 5.6,** Transfer of Care: It is unclear what constitutes a "reasonable effort" to communicate with a primary care provider, as currently required by this section. Our members commented that they would not have the capacity to make a phone call for every prescription written nor, if primary care providers, have the capacity to receive such phone calls. Contacting a primary care provider would also not necessarily "ensure a safe transition of care" and this language raises liability concerns for clinicians.

   VMS Recommendations: (1) Remove the phrase "ensure a safe transition of care;" (2), add the ability of a designee to assist with this process; (3) state that sending a paper or electronic copy of a discharge note or relevant portion of a paper record satisfies the "reasonable effort" requirement.

8. **Section 6.0,** Chronic Pain: With the changes to the overall rule, it has become unclear how this section regarding chronic pain relates to the other requirements of the rule.

   VMS Recommendation: As stated above, the rule should be clarified to state that the exemptions in Section 9.1 apply to the entire rule, so it is clear that they also apply to Section 6.0. It should also be clarified how this Section 6.0 relates to the requirements of Section 4.0. Since Section 4.0 only applies to initial prescriptions, if it is the intent of the Department, it may be helpful to clarify in Section 6.0 that the requirements of Section 4.0 would also apply if the prescription for treating chronic pain is the initial prescription by this prescriber.

9. **Section 7.0**, Prescribing to Minors: As drafted, this section leaves many unanswered questions for prescribers as it is unclear how it relates to the other sections of the rule, especially section 5.0. For example, in addition to the requirement to contact a primary care provider under 7.1, do prescribers also have to contact the PCP after ending treatment for pain (under Section 5.6)? Section 7.2 states that opioids shall not be prescribed for minor injuries as described in section 5.1.1, but section 5.1.1.2 does allow opioids for minor procedures – does this not apply to minors? Section 7.3 states that the cap of 24 MM Daily Dose and 0-3 days does not apply to "major surgery" or "multisystem trauma." Does this mean that the other exemptions in Section 9.2 (post-operative complications, medication assisted treatment or those who are opioid naïve) do not apply to minors? Does Section 9.1 (exemptions for cancer, palliative care, hospice, etc) apply?

   VMS Recommendations: Rather than creating a stand-alone section for minors with unclear relation to the remainder of the rule, the requirements for minors should be integrated into the other sections of the rule. The maximum dosages should be reflected in section 5.0 that also contains the maximum dose for adults (see proposed amendments section 5.2.2). As prescribing for minor procedures and communicating with providers are already addressed in section 5.0, sections 7.1 and 7.2 should be removed and addressed through section 5, consistent with adults, in order to avoid unnecessary complexity and confusion in implementing the rule.

10. **Section 9.0**, Exemptions. As discussed above, aspects of the exemptions lack clarity in scope and application.

    ***VMS Recommendations*:** Section 9.1 should be reworded to make clear that these exemptions apply to the entire rule. An overall exemption should be added for the administration of medication to a patient in a facility, as the requirements for informed consent and checking VPMS are inappropriate in mid-trauma or operative situations and it is unclear, as drafted, whether this would be required. Should one of these exemptions apply, the exemption should not need to be separately documented in the medical record (as required by Section 9.3) as it should be clear from the medical record itself that one of these circumstances is applicable. Finally, Section 9.2, dealing with exemptions to Section 5.0, should be moved to Section 5.0 to minimize confusion and assist with implementation.

11. **Overall rule**: The rule as drafted, and even with VMS recommendations, is lengthy and complex and will prove challenging for prescribers and facilities to implement.

    VMS Recommendation: The Department of Health should draft an FAQ or guidance document for prescribers explaining the steps and limits applicable when prescribing an opioid in chronic or acute situations.

Vermont Prescription Monitoring System Rule

1. **Sections 2.0, 3.2, 6.2, Exemptions**: As drafted, the exemptions to querying the Vermont Prescription Monitoring System when treating cancer and other end-of-life conditions are found in multiple locations with slightly different wording in each instance. See sections 2.0 ("cancer, hospice care and other end-of-life care"), 3.2 ("not caused by cancer or end-stage terminal disease"), and 6.2 ("nonpalliative").

   ***VMS Recommendation**:* To ensure consistency, clarity and appropriate pain control, the rule should contain a clear exemption section that lists exemptions with the same language found in Section 9.1 of the Draft Rule Governing the Prescribing of Opioids for Pain: "pain associated with active and aftercare cancer treatment; palliative care; end of life and hospice care; patients in skilled and intermediate care nursing facilities; and other circumstances as determined by the Commissioner of Health. " This approach is consistent with that taken in section 4.5 of this rule, which clearly lists exemptions from reporting to VPMS.

2. **Section 6.2.1**, Prescriber-required querying of VPMS**:** Section 6.2.1 of the draft rule would require a query of the VPMS in every instance that a provider prescribes an opioid Schedule II, III or IV to treat pain – both chronic and acute. While supporting the overall goal of checking the VPMS, there are instances when checking the VMPS for every opioid every time is particularly administratively burdensome and low-yield. VMS members are unaware of evidence that querying prescription monitoring programs before every prescription is likely to measurably reduce illicit or inappropriate prescribing or use**.**

***VMS Recommendation*:** Section 6 should contain additional exemptions for when a query of the VPMS is not required. These recommendations are consistent with the exemptions found in many other states including those adjacent to Vermont.[4] These exemptions should include:

- When treating acute pain post-operatively for no more than 7 days
- 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

In both of these instances, prescribers would by and large make the same prescribing decisions regardless of the information contained in the VPMS, making the requirement's burden outweigh any potential benefit. If the prescriber determines that a refill is needed, the prescriber would be obligated to query the VPMS at that point.

In addition, listed exemptions should include:

- "When administering medication to a patient in a health care facility licensed by the Department" – consistent with the exemption for reporting to VPMS in this instance (Section 4.5.1) and the infeasibility of stopping mid-procedure or emergency to check VPMS
- "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" – this is consistent with the required exemption found in Act 173 (Section 2 (d)) for cases of electronic or technological failure and is especially necessary in light of the proposed removal of section 7.3 allowing alternative arrangements for requesting data. It is also necessary in the cases of treatment in nontraditional settings, such as a sports medicine physician providing acute emergency care at a sporting event.

3. **Section 6.2.4**: Requiring a VPMS query "at least annually for patients who are receiving ongoing treatment" with an opioid. VMS members were unclear how "ongoing treatment" is defined – must it be continual for the year?

   VMS Recommendation: "Ongoing treatment" should be further defined.

4. **Section 6.2.3**: This section of the draft rule requires a prescriber to query the VPMS the first time a provider prescribes a benzodiazepine. VMS members were unclear of the intent of

[4] See, for example, New Hampshire's Rule Med 502.05, exempting when controlled medications are to be administered to patients in a health care setting, in cases of "treating acute pain associated with serious traumatic injury, post-operatively, or with an acute medical condition, with clear objective findings by the practitioner, for no more than 30 days; New York Public Health Law § 3343-A (2)(A), exempting use on the premises of an institutional dispenser, prescribing in the emergency room for less than 5 days, and when is it not reasonably possible for the practitioner to access the registry; Massachusetts Department of Public Health Rule 700.012 (H)(3) exempting prescriptions from the Emergency Department for up to 5 days; when emergency care is needed and use of the program may lead to patient harm; care to hospital inpatients or for immediate treatment; when it is not reasonably possible to utilize the program.

this addition – is it only when linked to concurrent opioid prescriptions? If so, wouldn't this be caught with the query when beginning an opioid? If not, why are just benzodiazepines required rather than other hypnotics? What is the evidence-base for this addition?

VMS Recommendation: Clarify the intent and/or requirement of querying for every first-time benzodiazepine.

5. **Sections 6.1.3, 6.1.4, 7.1.5, Out of state prescribers:** The draft changes the rule by removing sections related to out of state prescribers treating Vermont patients being required to register with or allowed to query VPMS. It is unclear to VMS why these sections are being removed.

   ***VMS Recommendation*:** The Department should ensure there are mechanisms for out-of-state prescribers to register with and query the VPMS.

6. **Section 8.1**, Disclosing Information from the VPMS: This section describes when the Department may send unsolicited reports to prescribers or share information with a licensing authority. VMS members support the use of VPMS and want the information to be as clinically useful as possible.

   ***VMS Recommendation*:** To help ensure that VPMS data is useful for prescribers now required to register and query the database when prescribing for individuals, this section should contain an additional requirement that the Department send prescribers annual reports of the prescriber's controlled substance prescribing history that includes patient-level reports and summary reports. VMS also recommends that the rules contain a new sub-section that requires the VPMS to have the functionality to integrate with electronic medical record systems used by prescribers in the State. While largely supporting the use of VPMS, prescribers have experienced administrative problems and delays due to the need to log into a stand-alone database. If prescribers need to query VPMS in almost all instances of prescribing opioids, it should be made as administratively seamless as possible. This integration has been accomplished in states such as Ohio.

7. **Section 8.2**, Correction of information: The draft changes propose removing Section 8.2, which allows prescribers or others to correct information contained in the VPMS database. It is unclear to VMS why these sections are being removed.

   ***VMS Recommendation*:** The Department should ensure there is still a mechanism for prescribers to correct information contained in the VPMS database.

3. Process Concerns

Act 173 states that "The Commissioner of Health, *after consultation with* the Controlled Substances and Pain Management Advisory Council, shall adopt rules governing the prescribing of opioids" (Section 2a) and that "The Commissioner *and the Council* shall consider additional circumstances under which health

care providers should be required to query the VPMS, including whether. . . prior to writing a prescription or any opioid Schedule II, III or IV controlled substance. . .." (Section 2(e)). See also Section 14 (e) of the Act: "The Commissioner of Health may adopt rules pursuant to 3 V.S.A. chapter 25 regarding the appropriate use of controlled substances in treating acute pain and chronic noncancer pain; the appropriate use of the Vermont Prescription Monitoring System; and the prevention of prescription drug abuse, misuse, and diversion, *after seeking the advice* of the Council."

After the passage of Act 173, the VDH did identify members of the newly-created Council, according to Section 14 of the Act. However, before promulgating these draft rules, the VDH convened the Council for one 2-hour meeting on July 21, 2016. At that meeting, the VDH shared a slide presentation with the Council that outlined some possible requirements for prescribing and VPMS rules but did not subsequently convene the Council to seek input on rulemaking nor shared further drafts of the rule with the full Council. VMS was optimistic that the VDH would rely on the diverse expertise of the Advisory Council to craft meaningful opioid and VPMS guidelines. While we appreciate the efforts of the VDH to also reach out to individual medical specialty societies and clinicians to gather feedback in the pre-rulemaking process, **VMS believes that holding one meeting of the Council does not meet the legislative intent of "consulting with" or "seeking the advice of" the Council nor did it optimize the expertise available to the Department to craft evidence-based rules**.

***VMS Recommendation*: The VDH should delay the rulemaking process while it seeks more meaningful input of the Council**. As demonstrated by the number, breadth and depth of comments received by the VMS, including by members of the Council (see Appendix A), there is still work to be done to build consensus among clinicians and reflect best clinical practice in crafting opioid prescribing and VPMS requirements.

Thank you for considering the comments of Vermont Medical Society members and we look forward to working with the Department of Health in the process of crafting policy for opioid prescribing that works for clinicians, patients and the State. Please let us know if you have any questions or if we can be of further assistance.