Date: August 2, 2016

To: Harry Chen, MD, Commissioner, Vermont Department of Health

From: Jessa Barnard, Esq., General Counsel & Vice President for Policy; Paul Harrington, Executive Vice President

CC: David Englander, Senior Policy and Legal Advisor, Vermont Department of Health; Vermont Medical Society Council; VMS Opioid Task Force; VDH Controlled Substances and Pain Management Advisory Council

Re: **Vermont Medical Society Comments, Opioid Prescribing Pre-filing proposals**

Thank you for the opportunity to present comments from Vermont Medical Society members regarding the Department of Health's proposed steps to implement the requirements of Act 173. Following the July 21st meeting of the Controlled Substances and Pain Management Advisory Council, VMS staff circulated the VDH PowerPoint and a summary of the VDH proposals to the VMS Leadership Council and the VMS Opioid Task Force, a multi-disciplinary task force with more than 40 members. VMS received feedback on the proposals from a number of member-physicians, across a range of specialties, and we appreciate the opportunity to share this feedback with you in the pre-rulemaking stage.

We also appreciate the efforts of the VDH to reach out to medical specialty societies and other physicians to gather feedback in the pre-rulemaking process. However, we were concerned to hear that the Controlled Substances Advisory Council will not meet again during the rulemaking process as VMS was optimistic that the VDH would rely on the expertise of the Advisory Council to craft meaningful practice guidelines, as anticipated by the legislature and Act 173.

Below is a summary of the feedback we have received and VMS' recommendations regarding the VDH's current proposals.

1) Acute Pain Opioid Prescribing

The VDH presentation (slide #7) states the goal of creating clear limits for acute pain opiate prescribing based on condition, injury and post-op pain for initial prescription, including clear guidance that allows for clinical judgment. **VMS fully supports this stated goal and our members have expressed support for prescribing guidelines based on specialty, including a role for limits on initial prescriptions.**

Slide # 9 of the VDH presentation includes a draft matrix for prescribing based on severity of the pain and severity of the condition, with the prescription always being less than 7 days. Our members provided several points of feedback on this proposal, including:

- Concern for how "mild" and "severe" pain or conditions will be defined and operationalized – for example, would a prescription have to state for "mild" or "severe" conditions?

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- Questions regarding whether the matrix is binding and built into a rule or simply providing practice guidance? Pain is complex and subjective and members responded that someone who has a "minor" procedure with "severe" pain may need more than three days of opioids – is three days recommended or a firm limit?
- Serious concern with a firm 7-day limit on all initial opioid prescriptions, especially in the context of post-surgical recovery or following a serious trauma. In those cases, while it may be appropriate to begin tapering medication quickly, certain patients may continue to require intermittent opioids (for example, at night) for longer than 7 days. This can be anticipated at the time of the initial prescription and requiring an additional visit is burdensome and expensive for patients and physicians alike, especially in a rural state like Vermont where it may be difficult for patients to access their physicians or pharmacies. In addition, a one-size-fits all opioid prescribing limit for acute pain could have unintended consequences including leaving patients without adequate pain control or leading physicians to seek "work-arounds" such as referring all follow-up pain needs to primary care providers, post-dating second prescriptions – leading overall to more medication than may be necessary, or referring patients who require surgical procedures that have more painful recoveries to out-of-state facilities.

VMS recommendations:

- **The VDH not include in rule a firm cap on the number of days for all initial opiate prescriptions**. Any cap on number of days for initial acute prescriptions should be contained in practice guidelines that allow for variance above that number based on clinical judgment and patient condition. Nothing in Act 173 requires the adoption of a firm cap and Act 173 requires that any limits are "consistent with evidence-informed best practices for effective pain management."
- Rather than creating one rule that applies across all specialties, **VDH support the creation of specialty-specific practice guidelines, consistent with best clinical practice and applied in individual patient cases**, such as the Consensus Statement created by emergency department directors.[1] **Such practice guidelines can contain appropriate suggested maximum durations of treatment**, such as the three days in the ER Consensus Statement (see section 6 (c)(vi)), as well as address appropriate alternatives to opiates, screening tools, prescribing tools and the frequency of VPMS use that would make sense in the context of specific types of treatment.

  Rushing the implementation of a firm limit undermines significant work that practices and facilities across the state are engaging in to develop protocols and tools to address opiate prescribing, such as the study UVM-MC is conducting this summer to determine if patients were prescribed the appropriate amount of analgesic medicine following a range of surgical procedures. A one-size fits all solution appears unnecessary at this time especially in light of the fact shared at the July 21st Controlled Substances Advisory Council meeting that 2015 VPMS data shows a decrease in opiate prescribing.
- **Any caps contained in guidelines should have explicit exceptions when opioids are prescribed for: active or aftercare cancer treatment; palliative care; end-of-life and hospice care; and medication-assisted treatment for substance use disorder**. Exceptions should also include

[1] See: http://legislature.vermont.gov/assets/Documents/2016/WorkGroups/Senate%20Health%20and%20Welfare/Bills/S.201/W~Dr.%20Mark%20Depman~Opioid%20Presribing%20Guidelines~1-27-2016.pdf

when the medication is directly ordered or administered in an emergency room, inpatient hospital or long-term care or residential facility.

2) Lower Dose for Children

Slide #10 of the VDH presentation proposes to set a lower limit for opioids for patients under 20 years old, for example, 3 days or 10 tabs. While most members supported some lower limit for children, feedback included:

- Questions regarding the evidence-base for a 3-day/10 pill limit– is this limit arbitrary or based in evidence regarding how much pain medication is effective in children? Act 173 requires that any limits are "consistent with evidence-informed best practices for effective pain management."
- Concerns for unintended consequences, such as dentists and emergency/urgent care clinicians sending more or all children to their primary care provider for follow up or to refill prescriptions if pain continues.

VMS recommendations:

- **Any cap on the number of days for initial acute prescriptions for children should be contained in evidence-based guidelines that allow for variance above that number based on clinical judgment and patient condition.**

3) Vermont Prescription Monitoring System

The VDH proposes to require that prescribers check the Vermont Prescription Monitoring System (VPMS) the first time the prescriber writes a prescription for a controlled substance to treat pain – both chronic and acute. Checking the VMPS for every opioid every time is 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 recommendations:

- **Queries of the VPMS should not be required by rule for every initial prescription**, especially when prescribed for post-operative care or for every trauma or serious acute injury in the emergency department, where checking this VPMS would take time and be likely to have low yield. New Hampshire's rule on opioid prescribing, for example, exempts checking 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."[2]
- **Requirements to check the VPMS should be included in specialty-specific practice guidelines that can be tailored to the needs of the clinicians and patients in given situations.**
- **Any requirement to check the VPMS should have explicit exceptions** when controlled substances are prescribed for: active or aftercare cancer treatment; palliative care; end-of-life and hospice care.
- Exceptions should also include: when the medication is directly ordered or administered in an emergency room, inpatient hospital or long-term care or residential facility; and in the cases of

[2] NH Rules Med 502, available at https://www.nh.gov/medicine/documents/opioid-rules.pdf

technical difficulties, technological failure or when it is not reasonably possible for the practitioner to check.[3]

- **VPMS is most effectively used as a peer review tool** and VPMS data should be shared with prescribers through a VDH-led peer review process to review and improve prescribing practices.
- **VPMS continue to make improvements** in terms of timeliness, accuracy and sharing of data and have the funding and staff necessary to do so. The VPMS is a work in progress and steadily improving, but it has taken longer than expected. Prescribers need access to useful data when checking the VPMS.

4) Informed Consent

Act 173 requires that VDH rules include informed consent for patients prescribed opioids. While some members have expressed concern regarding the administrative burden involved in providing a specific informed consent document to all patients prescribed an opioid, overall, **VMS supports informed consent and patient education and appreciates the VDH's efforts to create a model informed consent document for clinicians to distribute.**

VMS recommendations:

- **VDH develop more than one informed consent model**. Many patients who could benefit from taking opioids, such as palliative care patients, cancer patients, hospice patients and end-of-life patients, could be deterred from taking opioids by specific informed consent lists that are not designed for their condition. For example, informing patients about the risks of opioid addiction/dependence is not relevant for dying patients, whose treatment goal is comfort. The VDH should create a separate document, drafted in consultation with palliative care clinicians, for those patients.
- **Any informed consent documents created by VDH should be a suggested model, not a requirement**, so that the information can be more easily changed over time and so the information can be built into an EHR or shared with patients in different formats.
- For non-end-of-life/hospice/palliative care patients, **VDH should consider adopting the same or similar informed consent document as developed by the CDC** and American Hospital Association, so that information distributed is consistent with other states and locations: https://www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf

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.

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[3] 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, and 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.