October 28, 2016

David Englander, Esq.
Senior Policy and Legal Advisor
Vermont Department of Health
108 Cherry Street
Burlington, VT 05402

Dear Mr. Englander:

The American Osteopathic Association (AOA) is writing to request amendments to the proposed Rule Governing the Prescribing of Opioids for Pain (Rule). The osteopathic medical profession recognizes the urgency of the current opioid epidemic being faced by our entire nation, and by Vermont in particular. We have been heavily involved in efforts to address this issue through our collaborations with states, the Administration and within the health care profession. We understand the need to reduce opioid misuse and diversion and provide treatment to patients with opioid use disorders. We therefore strongly support the spirit behind Vermont's efforts to establish guidelines around opioid prescribing in the state.

The proposed Rule also requires prescribers to consider and document nonopioid and nonpharmacological treatments for pain management. While the proposal includes acupuncture and physical therapy in the list of nonpharmacological approaches to pain treatment, we note that it fails to include osteopathic manipulative treatment (OMT), an evidence-based approach that has been proven effective in managing pain in a number of conditions.1,2 Further, the AOA supports the pain treatment definitions and recommendations set forth by the Food and Drug Administration (FDA) and the 2016 Centers for Disease Control Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline), which differ from the proposed Rule in several areas. The AOA therefore requests amendments to include osteopathic manipulative treatment within the list of nonpharmacological approaches to pain treatment.

The AOA represents more than 123,000 osteopathic physicians (DOs) and osteopathic medical students, promotes public health, encourages scientific research, serves as the primary certifying body for DOs and is the accrediting agency for osteopathic medical schools.

DOs emphasize a whole-person approach to treatment and care, and receive special training in the musculoskeletal system and OMT above and beyond their allopathic physician colleagues. OMT is a

therapeutic application of manually guided forces by an osteopathic physician to improve physiologic
function and/or support homeostasis that has been altered by somatic dysfunction.\textsuperscript{3} It has also been
shown to help alleviate pain in patients while requiring significantly less medication and less physical
therapy than patients receiving standard care.\textsuperscript{4,5,6,7} The effectiveness of OMT as a nonpharmacological
alternative to opioids was recently recognized by the West Virginia Attorney General’s Office in their
Best Practices for Prescribing Opioids guideline, as well as by the Ohio Governor’s Cabinet Opiate
Action Team’s Guideline for the Management of Acute Pain Outside of Emergency Departments. More
information on DOs/osteopathic medicine can be found at www.osteopathic.org and
www.doctorsthatdo.org.

Misuse and diversion of controlled substances, as well as addiction and overdose, are significant and
growing public health problems that must be addressed through a multi-pronged public health
approach. We strongly support working to minimize the misuse and diversion of prescription drugs by
educating patients on the risks of opioids and on alternative treatments, as well as lessening the severity
of an overdose through the co-prescribing of naloxone. We also believe that adherence to the guidelines
and definitions promulgated by the CDC and the FDA will help combat this epidemic by unifying state
efforts and standardizing prescriber approaches nationwide. The CDC does not hold prescribers to
certain dosage or time limits for opioid prescriptions, yet the proposed Rule contains rigid limits based
upon the type and severity of a patient’s injury. The AOA believes that every patient and his or her
circumstances are unique, and physicians must be able to use their expertise and independent medical
judgment to diagnose and create a treatment plan that will best serve the individual patient’s needs. Hard
limits that interfere with this ability may prevent patients with legitimate pain care needs from receiving
timely and appropriate treatment.

The AOA respectfully requests the following technical and substantive amendments (and
renumbering of subsequent sections) to align with the CDC and FDA guidelines, and related
actions in other states.

1. “3.14 ‘Osteopathic Manipulative Treatment (OMT)’ means the therapeutic
application of manually guided forces by an osteopathic physician (U.S. usage) to
improve physiologic function and/or support homeostasis that has been altered
by somatic dysfunction.

2. “3.156 ‘Opioid naïve’ means a patient who has not used opioids in the past 30 days,
excluding any opioids administered in an inpatient or hospital setting. (also known as
‘opioid non-tolerant’) means a patient who does not meet the following definition
of opioid tolerant, and who has not taken opioid doses at least as much as those
listed below for one week or longer:

‘Opioid tolerant’ means a patient who has been taking, for one week or longer, at
least:

\textsuperscript{4} BMC Musculoskeletal Disorders. 2005; 6:43. 10.1186/1471-2474-6-43.
\textsuperscript{7} BMJ 2015; 350:g6380.
- 60 mg oral morphine/day;
- 5 µg transdermal fentanyl/hour;
- 30 mg oral oxycodone/day;
- 8 mg oral hydromorphone/day;
- 25 mg oral oxymorphone/day; or
- An equianalgesic dose of any other opioid.”

3. “4.1 Consider Non-Opioid and Non-Pharmacological Treatment…

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Acetaminophen
- Osteopathic Manipulative Treatment (OMT)
- Acupuncture
- Chiropractor or
- Physical therapy”

4. In order to align Section 4.4 with CDC Guidelines, the AOA recommends the following changes:

“4.4.1 Prescribers shall co-prescribe naloxone for all patients receiving an opioid prescription that exceeds a Morphine Milligram Equivalent Daily Dose of 90.”

6. The AOA recommends the following deletions that will allow the rules to provide a framework for prescribers to exercise their independent medical judgment on an individualized basis, which aligns with the CDC Guideline as well as the intent expressed in this document:

“5.1 Maximum Morphine Milligram Equivalents

The framework provides four categories, each with its own limits, described below and shown in Figure 1.0. Common Morphine Milligram Equivalent conversions are shown in Figure 2.0. The category into which a patient is placed is based on the medical judgment of the prescriber. Doses higher than those described in this section Figures 1.0 and 2.0 may be exceeded consistent with Section 5.4, but must be justified in the medical record.”

“5.1.1.1 Opioids shall be avoided in the treatment of pain associated with a minor injury, condition or procedure.”

“5.1.1.2 Should a provider need to use an opioid for a specific reason, that reason must be justified in the patient’s medical record and should not exceed a (Q1 in Figure 1.0):

- Total prescription of 72 Morphine Milligram Equivalents;
- 24 Morphine Milligram Equivalent Daily Dose; and
- Total of 0-3 days.”
5.2.1.1 Moderate Pain (Q1 in Figure 1.0): If the patient is experiencing moderate pain levels prescribers shall not exceed:

- Total prescription of 72 Morphine Milligram Equivalents;
- 24 Morphine Milligram Equivalent Daily Dose; and
- Total of 0-3 days.

5.2.1.2 Severe Pain (Q2 in Figure 1.0): If the patient is experiencing severe pain levels prescribers shall not exceed:

- Total prescription of 96 Morphine Milligram Equivalents;
- 32 Morphine Milligram Equivalent Daily Dose; and
- Total of 0-3 days.

5.2.3.1 Moderate Pain (Q3 in Figure 1.0): If the patient is experiencing moderate pain levels prescribers shall not exceed:

- Total prescription of 120 Morphine Milligram Equivalents;
- 24 Morphine Milligram Equivalent Daily Dose; and
- Total of 1-5 days.

5.2.3.2 Severe Pain (Q4 in Figure 1.0): If the patient is experiencing severe pain levels prescribers shall not exceed:

- Total prescription of 160 Morphine Milligram Equivalents;
- 32 Morphine Milligram Equivalent Daily Dose; and
- Total of 1-5 days.

5.4 Maximum Prescribing of Opioids for Acute Pain

Except as provided in Section 9.0, providers shall not exceed:

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

7. The AOA recommends the following addition to align with federal DATA 2000 rules for buprenorphine:

6.2.4 That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone or buprenorphine from an OTP or authorized and waived prescriber, or prescribed and taken any other controlled substance.

8. 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 indicators. Patients who are starting opioid therapy should be reevaluated within one to four
weeks. 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…”

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“7.3 Acute dosing for children minors should be proportional to weight…”

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“8.2 Prescribers subject to this section shall schedule and undertake periodic follow-up visits and evaluations (no less frequently than every 180 days…”

Chronic pain is a devastating affliction that impacts millions of American lives. The AOA supports a variety of approaches to limit abuse and misuse and prevent opioid use disorders and overdoses, while ensuring that patients with legitimate needs maintain access to pain care and treatment. We appreciate your consideration of our request to amend the Rule. Should you need any additional information, please feel free to contact Nicholas A. Schilligo, MS, AOA Assistant Vice President of State Government Affairs, at nschilligo@osteopathic.org or (800) 621-1773 ext. 8185.

Sincerely,

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President, AOA

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