



October 28, 2016

David Englander and Shayla Livingston
Department of Health
108 Cherry Street
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Ahs.vdhrules@vermont.gov

RE: Rule Governing the Prescribing of Opioids for Pain

Dear Mr. Englander and Ms. Livingston:

Collectively, the undersigned organizations wish to offer the following comments for consideration, with respect to the Department of Health's proposed *Rule Governing the Prescribing of Opioids for Pain*. Representing tens of thousands of people living with pain, as well as many thousands of clinicians who care for them, our organizations recognize the challenges involved in addressing two major public health crises, namely, inadequate treatment for pain and prescription drug abuse. To that end, we have been heavily involved in both national and state-level efforts to address both health concerns. In response to the proposed rule, we respectfully offer the following comments.

Section 4.1

The undersigned organizations believe that optimally treating pain requires an integrative model of care, which: is patient-centered; considers the whole person; encourages healthful lifestyle changes as part of the first line of treatment to restore wellness; is evidence-based; brings together all appropriate therapeutic approaches to reduce pain and achieve optimal health and healing; and, encourages a team approach. However, despite our strong support of access to, and reimbursement for, non-opioid and non-pharmacological treatments, we cannot support this provision as it is currently drafted. As written, this section appears to *require* considering and documenting *all* non-opioid or non-pharmacological treatments, whether or not those treatments are applicable to the patient's individual situation. This is neither feasible nor necessary.

Recommendation: We suggest that the provision be amended so that the prescriber must only consider appropriate/applicable alternatives and document in the patient record only those treatments that were actually recommended.

Section 5.0 (5.1-5.4)

We have significant concerns with this section—we believe it is not supported by adequate evidence and further, that it will prove confusing to clinicians and difficult, if not impossible, to implement.

Section 5.0 states that this section provides a “framework” for prescribing and that the doses “may be exceeded consistent with Section 5.4.” In 5.4, we see that these are “maximum prescribing” rules for acute pain, but even these have exceptions found in 9.0. In 9.0, there is a list of exemptions from the rule, many of which are not supported by the evidence (see “Section 9.0”, below) and are in need of further definition. To further complicate matters, Section 5.1.1.1 states that opioids “shall be avoided”, but Section 5.1.1.2 goes on to create rules for use “should a provider need to use an opioid.” This confusion is furthered by Section 9.2, which states that the exceptions apply to the “limits on opioid medication prescribing established in Section 5.0 of the rule”—but it seems to us that the intent was that Section 5.4 is the only portion of Section 5.0 that provides a binding limit. It is entirely unclear if Section 5.0 is binding upon prescribers or if it merely provides guidance.

We are extremely concerned that even the most well-meaning clinicians will not be able to navigate this rule, inadvertently running afoul of it despite trying their utmost to follow the letter of the law. The complexity of the matrix presented by Section 5.0 will first require a clinician to categorize a procedure based on its severity, then analyze the level of pain being experienced by the patient, then look to the limits of 5.4, and then look for an exception in Section 9.0 (to be followed by the other *many* requirements of this rule pertaining to naloxone, PMP checks, informed consent, and more).

Further, we are concerned with the dosage and duration limits that have been selected. First of all, AIPM only supports dosage and duration *thresholds* that trigger re-evaluation, not *limits* that arbitrarily control patient care. Further, we believe that these thresholds should never be legislated or regulated as hard limits, but rather, put forth as recommendations in guidelines. Each patient’s situation is unique and optimal care requires individualized treatment that cannot be pre-determined through legislation or regulation. Secondly, we are concerned that the morphine milligram equivalent levels and duration limits that have been chosen in this rule are very low—for example, the 24 MME/day limit in 5.1.1.2 and 5.2.1.1 is not enough medication to cover a patient around the clock unless a hydrocodone combination product with only 2.5 mg of hydrocodone has been prescribed (30 MME/day is the minimum to cover around the clock).

We are also concerned with this section’s use of the word “evidence.” Numerous times throughout the section, the rule defines minor, moderate, and major injuries or procedures as “one for which evidence shows” that opioids or non-opioids are effective. What evidence? It is unclear from this rule what evidence the rule is contemplating when making these determinations, and more importantly, it is unclear what evidence a prescriber is expected to utilize when making these determinations. Additionally, we are unaware of any evidence of the sort that appears to be contemplated by this rule.

Recommendation: This section should be amended to clarify that it provides guidelines and *not* binding limits. In so doing, attention should be paid to changing “shall” to “should” (or “should consider”) throughout the rule, particularly in 5.1.1.1.

These guidelines should be based purely on the patient’s level of pain and all references to the severity of the procedure should be deleted.

The overall limits for prescribing for both adults (Section 5.4) and children (Section 7.3) should be stated clearly in one place. The overall limits *and* the exceptions to those limits should be stated *before* Section 5.1 in order to create an understandable flow for the prescribers who will have to implement and comply with this rule. Further, the section should clearly state that refills consistent with state law are not precluded.

Section 6.0

With the changes to the overall rule, it is unclear how Section 6.0 relates to the other requirements of the rule.

Recommendation: The rule should be clarified so that it is clear that the exceptions found in 9.0 apply to Section 6.0. Further, the connection between Section 4.0 (initial prescriptions) and Section 6.0 must be clarified.

Section 7.0

Our first concern with this section is in its introductory language that considers minors to be “anyone ages zero to eighteen.” Being that one reaches the age of majority at eighteen, we believe this language should read, “...anyone ages zero to seventeen.”

Our next concern is that it is unclear how this section applies to Section 5.0. Section 7.2 states that opioids shall not be prescribed for minor injuries as described in Section 5.1.1. However, Section 5.1.1.2 does allow opioids for minor procedures—does this apply to minors? Further, the exceptions found in Section 9.0 are not mentioned in Section 7.0—do those exceptions apply to minors?

Our final concern of this section is the mandate in 7.3 that states “When prescribing an opioid for anything less than major surgery or multi-system trauma, prescribers shall not exceed a [...] total of 0-3 days. This is a huge concern, as Section 7.0 is not limited to acute pain. If this provision is not limited to acute pain, the rule is essentially prohibiting the use of opioids for the treatment of chronic pain in minors, including pain associated with a terminal cancer diagnosis (depending upon whether or not the exemptions in Section 9.0 apply to Section 7.0, which, again, is unclear from the rule as it is currently written). If this portion of the rule is incorporated into Section 5.0, as we recommend, the provision will only apply to acute pain and our concern will be resolved.

Recommendation: Change “anyone ages zero to eighteen” to “anyone ages zero to seventeen.”

Integrate the portions of this rule that apply to minors directly into the other sections of the rule in order to aid prescribers in implementing the rule. As we noted under Section 5.0, the overall limits for prescribing for both adults (Section 5.4) and children (Section 7.3) should be stated clearly in one place. The overall limits *and* the exceptions to those limits should be stated *before* Section 5.1 in order to create an understandable flow for the prescribers who will have to implement and comply with this rule.

Section 9.0

The placement of these exemptions will make it difficult for a prescriber to properly implement this rule. Further, many of the terms used in this section need to be defined.

Recommendation: Section 9.1 should be clarified so that prescribers understand that these exemptions apply to the *entire* rule. Further, an exemption should be added to this section for the administration of medication to a patient in a facility—the requirements for informed consent are inappropriate in mid-trauma or operative situations. Next, both “palliative care” and “end-of-life” need to be defined by the rule if they are to be understood equally by all, as they do not have inherently firm definitions. Finally, should one of these exceptions apply, the exemption should not need to be separately documented in the medical record as currently required by Section 9.3, as it should be clear from the medical record itself that one of these circumstances is applicable.

Section 9.2, which deals solely with Section 5.0, should be moved to Section 5.0 to enhance clarity and implementation.

We hope these comments are helpful and promote discussion of some of the important issues we have highlighted. As stated earlier, the undersigned organizations are committed to doing their part to improve care for people with pain, and in so doing, helping to mitigate the risks associated with such care. We thank you for your consideration of these very important issues.

Respectfully Submitted,

Academy of Integrative Pain Management
Alliance for Patient Access
American Association of Nurse Practitioners
Families for Intractable Pain Relief
National Association of Clinical Nurse Specialists
The Pain Community
US Pain Foundation