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243 Israel Road S.W.
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**Re: WSMA COMMENTS: Medical Quality Assurance Commission Proposed
Final Rules on Chronic Noncancer Pain Pursuant to HB 2876**

Dear Drs. Pattison and Brantner:

Pursuant to the requirement in HB 2876 that the Medical Quality Assurance Commission (“*Commission*”) consult with the Washington State Medical Association (“*WSMA*”) in developing new rules on chronic noncancer pain management, the WSMA submitted formal written comments to the Commission in September and November of 2010, as well as in-person feedback at multiple meetings during that same time period. Following publication of the Commission’s proposed final rule (CR-102) on January 18, 2011, the WSMA now wishes to provide the Commission with formal comments on its proposed final rule.

You will note that many of the WSMA’s comments are restatements of earlier comments. We have done so because many of those comments were not incorporated into the proposed final rule and we believe those comments are worth repeating, and deserve a further – and a fresh – look by the Commission. In short, the WSMA has significant concerns that the proposed final rule, which goes into great detail in dictating how physicians *shall* manage chronic noncancer pain patients, will result in a further shortage of physicians willing to treat patients suffering from noncancer chronic pain.

As one member commented in his feedback to us on the proposed final rules – a comment that is indicative of others we received:

“I don’t treat chronic pain, but if I did, review of these rules would cause me to desist! They are so specific I doubt anyone other than a pain specialist would be able to follow them as written. The level of micromanagement is astounding.”

The WSMA trusts you will find our comments helpful and the WSMA will work closely with the Commission to educate our physician membership about the new rules including any available information or tools to assist them with compliance.

Sincerely,

A handwritten signature in black ink that reads "Tim Layton". The signature is fluid and cursive, with the first name "Tim" and last name "Layton" clearly legible.

Tim Layton
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Washington State Medical Association
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WSMA COMMENTS & CONCERNS

THE LANGUAGE FROM THE FEDERATION OF STATE MEDICAL BOARDS' PAIN GUIDELINES IS NOT INCLUDED IN THE PROPOSED FINAL RULE

As stated in both our September 2010 and November 2010 comments, it remains quite concerning to the membership of WSMA that the Commission's proposed final rule continues to exclude the preamble language from the Federation of State Medical Board Guidelines on pain management that was included in the Commission's initial draft rules. On multiple occasions the WSMA was assured by Commission members that this language would be added back into the rule. We were quite surprised and disappointed to find that the language did not make into the now proposed final rule. ***The WSMA once again strongly recommends that this language be added to the proposed final rule, as well as incorporated into substantive sections of the rule.***

THE RULE GOES BEYOND PROVIDING GENERAL GUIDANCE REQUIREMENTS AND INSTEAD PROVIDES NUMEROUS SPECIFIC LEGAL MANDATES SURROUNDING THE MANAGEMENT OF CHRONIC NONCANCER PAIN

Other than the "dosing criteria" in Subsection 2(a) of Section 5 of HB 2876, all the remaining subsections (b) through (d) only require guidance: "Guidance on when to seek specialty consultation . . ." Section 5(2)(b); "Guidance on tracking clinical progress . . ." Section 5(2)(c); and "Guidance on tracking the use of opioids . . ." Section 5(2)(d).

The WSMA believes the rule, as the law provides, should be guidance for quality pain management care and not a restrictive legal mandate as to a specific manner/means of treatment. The WSMA's recommendation remains the same. The term "should" be used instead of the term "shall." The term "*should*" sufficiently establishes the standard of care that must be followed unless the physician can demonstrate sufficient rationale to act otherwise. The term "*shall*" establishes a rule of law that is prima facie evidence of unprofessional conduct and/or medical negligence should a physician not meet the standard of care. This is problematic for a number of reasons:

1. It creates additional liability for a physician who may be acting or performing best practices but fails to comply with one of the numerous criteria outlined in the proposed final rule.
2. The potential (real and/or perceived) for additional liability is likely to have the unintended consequence of (i) causing physicians to reconsider the treatment of non-cancer chronic pain patients as a risk management precaution, and (ii) unnecessarily

increase the time and cost to treat non-cancer chronic pain patients without tangibly improving the quality of care provided these patients.

3. It establishes a standard of care in law that cannot be readily changed as best practices evolve, as well as care protocols that may not be appropriate for all physician specialists who on occasion may be responsible for treating non-cancer chronic pain patients. For example, a surgical specialist may be reluctant to treat a current or prior chronic pain patient for fear that patient is likely to have additional recovery issues and thereby fall under the requirements set forth in the proposed final rule – a set of requirements the specialist may not be familiar with or comfortable fulfilling.

THE RULE REMAINS UNCLEAR AS TO WHOM AND WHEN IT APPLIES, WHICH IS LIKELY TO CREATE UNNECESSARY CONFUSION AND A RELUCTANCE TO TREAT CERTAIN PATIENT GROUPS

WSMA members have expressed continued concern that the definition of “*chronic noncancer pain*” in the proposed pain management rules can be interpreted to apply in situations to which it was not necessarily intended to apply.

EXAMPLE: Consider a situation in which a physician treats a patient for an acute injury or condition which improves, but which remains a source of pain lasting months or more beyond the usual course of the acute injury/condition. Currently, the physician may prescribe a small amount of a low-dose opioid regularly, which allows the patient to function well. Under the proposed rules, the patient would be considered to have chronic noncancer pain, and the physician would then be required to complete what, for someone who is not a pain specialist or primary care physician, are rather onerous evaluations, develop a complicated treatment plan for an otherwise uncomplicated problem, and perform detailed periodic reviews for patients who are functioning normally on a stable, non-escalating dose of medication. If the proposed final rule does not address situations such as this, then many treating physicians will just stop seeing patients who require low doses of medications for mild chronic pain. This will act to further overload primary care physicians and pain specialists.

EXAMPLE: Now consider a similar situation where a patient has persistent shoulder pain that his/her primary care physician treats for a period of four months with little to no success. That primary care physician then refers the patient to an orthopedic physician. When the patient arrives for consultation the orthopedic physician has no intention to treat this patient for chronic noncancer pain, but rather to rehabilitate the patient. However, pursuant to the definition of chronic noncancer pain the orthopedic physician may be legally required to treat the patient as a chronic noncancer pain patient and comply with all the requirements set forth in the rule.

We have heard from physicians who commented that rather than trying to comply with the rules in these situations they will simply stop seeing patients that fit this profile out fear of liability and possible licensure action.

The WSMA strongly recommends that the definition of chronic noncancer pain be amended so that it clearly indicates when someone is treating a patient for chronic noncancer pain.

COMMENTS REGARDING MORPHINE EQUIVALENT DOSE AND METHADONE

Physician members continue to raise questions about the use of MED tables to guide chronic pain, especially as it pertains to Methadone. Initial guidance in this area will be critical.

Also, the additional education requirements around the prescribing of methadone is probably a good thing; however, it appears inconsistent to single out Methadone for education while the state drug formularies indicate that Methadone is no less dangerous to prescribe than any other opioid. This inconsistency is confusing to prescribers. If these additional requirements are adopted they will need to be clearly noted on the state drug formularies to avoid non-compliance and possible liability exposure. For example, the proposed rule requires:

NEW SECTION

WAC 246-919-855 Informed consent. The physician shall discuss the risks and benefits of treatment options with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without health care decision-making capacity.

However, the Pharmacy and Therapeutics Committee within the Health Care Authority, by virtue of listing Methadone as "preferred," has reviewed the safety of Methadone and determined it is of similar safety to other long acting opioids. There are members of the physician community who feel that safety information driven by the state Preferred Drug List program introduces ambiguity into the informed consent process, and places patients at risk for adverse events relating to Methadone.

CONCERNS REGARDING THE DOSAGE AMOUNT

As previously noted, we have not received strong objection or support for the use of 120 MED as the dosage amount. The concern remains that the dosage amount is not backed up by strong scientific data (in fact we have heard everything from 200 MED all the way down to zero). It is an arbitrary number that may result in unintended consequences such as (i) creating an

unnecessarily high demand for consults whereby there are not enough pain specialists to meet the demand, or (ii) inadequate payment method (or non-at-all) for the mandated consults.

An alternative approach we suggested back in September and November would be to add another exception to the consult requirement related specifically to the dosage issue. The following approach, which we also included in our November 2010 comments, may achieve greater compliance with best practices while maintaining physician/patient autonomy.

“The provider shall obtain specialty consultation by a practitioner specializing in pain management when the patient’s dosage exceeds 120 mg morphine equivalents per day, unless after satisfying the best practices outlined in this rule the provider determines, and clearly documents in the patient’s medical record, the clinical basis for not seeking a consult, the reasonableness of the dosage amount being prescribed, and the evidence indicating that the treatment is within the usual course of treatment for similarly situated patients.”

In addition, there is also concern that there is no differentiation between enteral and parenteral administration of dosage amounts of opioid compounds, since the route of administration can have significantly different effects on patients.

Finally, it should be recognized that methadone poses particular problems in the treatment of chronic noncancer pain. Patients placed on methadone starting at doses under 120 MED, particularly who are not considered “opioid naïve” and are being switched to Methadone from high doses of other opioids, are at particularly high risk to bio-accumulate Methadone and succumb to respiratory failure within days of initiating Methadone. This has occurred in Washington State, and has incurred liability on the part of unsuspecting physicians who use MED “conversion tables” in the context of initiating Methadone. The 120 MED dose limit will increase the use of conversion tables, and also perhaps introduce a false sense of confidence at doses under the 120 MED limit. 120 MED of any opioid will have varying analgesic and toxic effects from patient to patient, and one drug to another. But the toxicity of Methadone is greater than other long acting opioids, with respect to respiratory depression, in relation to its analgesic potency. In addition, the analgesic potency will diminish in 8 hours, whereas the effects on respiratory depression will persist well beyond 24-36 hours. This analgesic/toxicity mismatch with methadone results in “stacking” where the patient accustomed to more frequent dosing (and pain relief) with a short-acting opioid may begin to “stack” analgesic relief with methadone, without realizing the toxic effects of the drug are accumulating. Lastly, Methadone will introduce risk for toxicity via QT interval prolongation, at doses under 120 MED. Therefore, a wholesale “risk threshold” of 120 MED may introduce unintended public health risk, due to the wide ranging complexities of methadone within the opioid class.

CONCERNS AND SUGGESTION ABOUT THE CME REQUIREMENT

The WSMA concurs that making completion of a CME requirement an exception to the requirement for consultation is a good idea. The 12 hours of CME every two years seems reasonable. The WSMA is aware that pain management CME courses are currently available and would be able to assist in making sure such programs are readily available within the time frames of this rule.

However, the WSMA has concern about the phrase in proposed WAC 246-919-862(2) which states that the pain management CME must be approved by “the profession’s continuing education accrediting organization.” There is no single organization in Washington State which is “the” medical profession’s CME accrediting organization. The WSMA acts to accredit other organizations to present Category I CME programs, and is itself an accredited CME presenter. But there are other CME accrediting organizations both in Washington and throughout the country. The WSMA would like the Commission to clarify which organization, or group of organizations, may accredit pain management CME programs that will satisfy the requirements of proposed WAC 246-919-862.

CONCERN WITH THE USE OF UNDEFINED TERMS

The term “*multidisciplinary chronic pain treatment center*” and “*chronic pain management setting*” are not defined, which could lead to confusion regarding both exemptions under proposed WAC 246-919-862 and qualifications for a pain management specialist under proposed WAC 246-919-863. Conceivably, any clinic or office that treats chronic pain patients might be considered a “chronic pain management setting,” though the expertise and resources of such a setting may be quite different than a multidisciplinary pain management program at facilities such as the University of Washington, Virginia Mason, or Swedish Medical Center. If the standards for exemption and status as a pain management specialist are to be valid, then the Commission may wish to consider adding more specificity to those terms.

The term “physician” is used throughout the proposed rules in Chapter 246-919 WAC. Since there are separate rules governing osteopathic physicians, the Commission may wish to consider relating the term “physician” in the Commission’s rule to the statutory definition for allopathic physicians.

CONCERN WITH THE QUALIFICATIONS TO BE A PAIN MANAGEMENT SPECIALIST

WSMA members have expressed concern that Advance Registered Nurse Practitioners (ARNPs) may qualify as pain management specialists under the proposed rules. ARNP training is

significantly less than that of a physician who has completed medical school, residency, and most likely a fellowship. Allowing an ARNP to meet the qualifications for being a pain management specialist merely by working in chronic pain management setting, which arguably could be a physician's office (*see concern about undefined terms above*), may not result in a uniformly high level of expertise for individuals authorized to manage the most challenging chronic pain patients. Further, the rules do limit the background of a pain specialist to whom a physician may or must refer patients under the proposed rules.

Meanwhile, a physician assistant performing tasks under the direct supervision (and pursuant to a practice management plan) of a qualified physician pain specialist is not listed as a pain specialist when performing acts in such capacity (*see comment below regarding physician assistants*).

THERE NEEDS TO BE ADDITIONAL CLARIFICATION REGARDING PHYSICIAN ASSISTANTS

The WSMA has heard concerns that the proposed pain management rules for Physician Assistants (PAs) might be interpreted to permit PAs to treat complicated chronic pain patients independently. There is no specific requirement that pain management activities be included in the approved practice management plan which must be on file at the Commission. **We think language should be added to the WAC to clarify the relationship of PAs who work for qualified pain specialists and the role of the practice management plan regarding PAs performing the functions of a pain management specialist.**

The WSMA also finds that the PA, as is current practice, should be able to work as an extension of their sponsoring physician, performing all appropriate procedures as approved by the Commission in the physician/PA practice management plan. This in turn would mean that the PA should be permitted to perform functions pursuant to their training and the approved practice management plan under a supervising pain management physician specialist. The PA, therefore, should also be deemed a pain management specialist when performing functions in that capacity. **The WSMA would support clarifying this important care team arrangement in WAC 246-918-813 as the section currently does not mention PAs.**

CONCERNS REGARDING THE USE OF A WRITTEN AGREEMENT AND PERIODIC REVIEW

The use of written agreements is an area of debate within the pain community with respect to the value of such agreements, and how to construct the agreement in order to build a positive relationship with the patient. Setting this particular agreement into state rule, rather than

establishing guidelines for maximizing compliance could diminish the physician/patient relationship in many cases. The physician's burden to manage compliance/non-compliance represents an under-explored area of liability and sanction risk. Placing the physician in the position of being a party to a behavior contract when the physician may have limited control over the patient's behavior could raise issues of negligence and/or unprofessional conduct in the event the patient fails to comply with the agreement.

The requirement to "periodically review" the patient would have to involve an "objective" review of pain, function, and quality of life. However, these are primarily subjective experiences, which are difficult to quantify objectively. Furthermore, if such qualities of life were to deteriorate while on opioids, the causality of such deterioration might be due to factors independent of the treatment modality. A patient who has pain and is placed on opioids, for example, and later suffers additional trauma or stress independent of the primary indication for the pain treatment; may display a diminishment in overall quality of life due to factors unrelated to the opioids. Requiring use of evaluation parameters that are imprecise and potentially misleading may not result in improved patient care or safety.

Cc: Dr. Les Burger; Chair, Medical Quality Assurance Committee
Maryella Jansen; Executive Director, Medical Quality Assurance Commission
WSMA Executive Committee
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Dr. Michael Schiesser
Gary Morse, General Counsel, Physicians Insurance A Mutual Company