September 29, 2014

Medical Board of California
Sacramento, California

RE: Draft Pain Management Guidelines

Dear Members of the Board:

I am writing today on behalf of the American Academy of Pain Management, to comment on your draft guideline, as referenced above. In general, I think these guidelines are sound, but there are a number of significant issues, as well as a number of grammatical/typographical issues, that I wish to address. I will list my concerns below.

- **Applicability to cancer pain**: It is our position that cancer-related pain and pain unrelated to cancer are no different in terms of their basic physiology. The nervous system activity that results in the experience of pain is no different if pain is caused by cancer or its treatment, or by another type of process. Additionally, opiate receptor function does not differ by virtue of the cause of the pain. The bottom line for us is this: If these guidelines are intended to protect people on long-term opioid therapy from adverse events, including abuse, addiction, and overdose, then it is irresponsible and inappropriate to exclude people with cancer from them. Cancer is no longer the death sentence it was 30 years ago; more than 60% of people diagnosed with cancer today will become long-term survivors, many of them due to the benefits of chemotherapy regimens that are very neurotoxic. These survivors may have life-long pain that may require long-term opioid therapy. These individuals need to benefit from the protections offered by your guidelines, so we respectfully suggest that you reconsider making a distinction between cancer-related pain and non-cancer-related pain.

- **Specific recommendations for people with cancer-related pain**: On page 5 of the guideline, there are two recommendations regarding treatment of cancer-related pain that I believe are incorrect or in need of revision. The first of these is the statement, “...a trial of opioid therapy should be administered to all cancer patients with moderate or severe pain...” This is erroneous. Some cancer survivors with moderate-to-severe pain benefit greatly from the use of non-opioid medications, and when these are effectively administered, opioids are unnecessary. Similarly, other treatments such as surgeries, radiation therapy, and other procedures may provide sufficient pain relief that opioids are not necessary. It is a serious overreach to recommend that all people with moderate-to-severe cancer-related pain should have a trial of opioid medications.
Similarly, the reference on page 5 to “patient-controlled analgesia with subcutaneous administration...” bears examination and, I believe, editing. Subcutaneous administration certainly is an effective means of delivering this type of care, but it is by no means the only way to do so, and may not be the best route of administration. Ambulatory patient-controlled analgesia can be administered via an intravenous route, which may be a much more reliable route of administration. My suggestion is that you delete the words “with subcutaneous administration”, as that specification is unnecessary.

- **Terminology:** Throughout the guideline, there are two terms that I would like to see changed. “Chronic opioid therapy” should be changed to “long-term opioid therapy”, because it is medical conditions that are chronic, not their treatments. Also, the term “pain management contract” should be replaced with “pain management treatment agreement”. These documents are not legally-binding contracts, and should not be presented as such.

- **Use of opioids to treat acute pain:** On page 4, the guideline states, “Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.” I believe this is an unnecessarily strong statement, and that it could lead to the undertreatment of acute pain in many patients. As written, this statement appears to require a trial of an unknown number of non-opioid medications before opioids can be used. In fact, in some instances, the pain may be of such a nature that any competent clinician would reasonably judge that an opioid is required before trying NSAIDs, acetaminophen, antidepressants, anticonvulsants, etc. I believe a better way to state this would be to say, “…after determining that other non-opioid pain medications or therapies likely will not provide adequate pain relief.” This allows for the clinician’s judgment.

- **Tapering of benzodiazepines:** On page 6, in discussing older adults, it states, ” Tapering of benzodiazepines is important to reduce the potential for respiratory depression.” My assumption is that this is intended to apply only in cases where opioids are used. I don’t think a blanket recommendation to taper benzodiazepines, regardless of the presence of opioids, is either intended or warranted. This can be fixed by adding “…respiratory depression in patients concomitantly using opioids or other respiratory depressant medications.”

- **Pediatric patients:** The text on page 6 is very poorly written, causing a lack of clarity. Further, this paragraph seems to apply only to adolescents. This paragraph needs extensive revision to improve clarity and to include the full range of children.

- **Patients prescribed methadone of buprenorphine:** On page 8, the guideline states, “Patients prescribed methadone or buprenorphine for treatment of a substance use disorder may need relief of pain not addressed by opiate agonists, such as due to an acute injury.” First, it is not clear to me what is meant by “relief of pain not addressed by opiate agonists”. Secondly, this text implies that the only reason these individuals would need pain treatment is in the case of acute pain, yet these individuals also may very well have chronic pain that may or may not be addressed by opiate agonists. I suggest revising this sentence to read, “Patients prescribed
methadone or buprenorphine for treatment of a substance use disorder may need relief of acute and/or chronic pain, beyond that provided by their maintenance medication.”

- **Establishing risk/benefit ratios:** On page 9, the guideline states that one part of patient evaluation and risk stratification is, “Establishing a benefit/risk ratio”. Certainly, one wants to consider both risks and benefits, and their relative importance and magnitude, but this phrasing suggests that it is possible to establish a number or other sort of summary conclusion about this ratio. I don’t believe that is possible. I suggest changing this to read: “evaluating both potential benefits and potential risks of opioid therapy”.

- **Content of pain management agreements:** On page 11, the guideline suggests that agreements contain language specifying “The patient’s responsibility to obtain his or her prescribed opioids from only one physician or practice.” Typically, we also suggest that these specify the responsibility to obtain prescribed opioids from only one pharmacy (or pharmacy chain). I suggest adding this language.

- **Percentage of overdose deaths occurring in people using medications as prescribed:** On page 11, the guideline states, “Given that approximately half of overdose deaths occur in persons who are using their medications as prescribed…” I am unaware of research to support this assertion, and it is not referenced. Research in West Virginia by Hall et al. demonstrated that as many as 65% of decedents did not even have a prescription for the opioid involved in their fatal overdose, much less that they were taking it as directed if they did. I suggest revising this sentence to read, “Given that overdose deaths can occur in people who are using their medications as prescribed…”

- **Unclear statement:** The following statement on page 13 is confusing to me: “Since opioids are known in some circumstances to worsen pain (hyperalgesia), instances of ongoing pain may suggest opioid insensitivity (or an inadequate dose).” Shouldn’t this read “Although opioids are known…instances of ongoing pain may also suggest…”?

- **Dosage recommendations for opioid naïve patients:** The examples provided on page 13 are confusing, inaccurate, and very poorly presented. For example:
  
  - Norco is recommended to be prescribed at a 5 mg (hydrocodone) dose. However, this specific product is only supplied in 7.5 mg and 10 mg hydrocodone doses, so to provide a 5 mg dose, the larger pill would have to be cut in half;
  - The equianalgesic ratios among codeine, hydrocodone, and oxycodone are calculated differently within the table. Under the TYLENOL # 3 bullet, 1 mg of hydrocodone = 8.33 mg of codeine and 1 mg of oxycodone. Under the VICODIN bullet, 1 mg of hydrocodone = 5.5 mg of codeine and 1.52 mg of oxycodone. And under the PERCOCET/ENDOCET bullet, 1 mg of hydrocodone = 5.5 mg of codeine and 1.5 mg of oxycodone.

  Additionally, the table mentions that tramadol is not reported to CURES, but now that tramadol is a C-IV controlled substance, it should appear in CURES.
This section with the examples is, frankly, so confusing and so poorly done that I see no alternative but to delete it and/or replace it with something that is more systematic, more accurate, and much easier to understand.

- **Equianalgesic conversion strategies**: I have one recommendation for this section on page 15. The text says that “... physicians may want to use initially lower-than-normal doses of the switched-to opioid.” Given that there is no such thing as a “normal” dose, I think this should be changed to read “... physicians may want to use initially lower-than-calculated doses of the switched-to opioid.” In a similar vein, let me suggest one additional equianalgesic conversion calculator, one that is based on a greater body of research than those you currently recommend. This calculator can be found at [http://opioidcalculator.practicalpainmanagement.com/](http://opioidcalculator.practicalpainmanagement.com/)

- **Drug testing**: This section on page 15 should specifically say that unexpected results from office-based testing MUST be confirmed by the more-sensitive laboratory testing before the patient’s plan of care is changed. Office-based testing is so unreliable that it would not be fair to patients if those results were acted upon without confirmation.

- **Consequences for evidence of misuse**: On page 16, the paragraph outlining consequences if there is evidence of misuse is incomplete. Additional consequences should be listed, specifically, an assessment for the presence of a substance use disorder and referral for appropriate treatment if one is found.

- **Pill counting**: On page 16, the paragraph about pill counting states, “Periodic (or more frequent, if necessary) pill counting...” In fact, “periodic” pill counting can vary with respect to the period—it can be monthly counts, weekly counts, daily counts, even hourly counts. I believe the intent here is to communicate that the periodicity of the count can vary depending on circumstances. I suggest deletion of the parenthetical phrase.

- **Unsanctioned dose escalation**: On page 17, the guideline lists reasons for discontinuing opioid therapy. In the last bullet of the list, a number of aberrant drug-related behaviors are listed. Two of these contain the caveat “although ensure that this failure is not the result of inadequate treatment”. I have two concerns: first, these are “behaviors”, not “failures”; and second, this caveat applies to most, if not all of these items. It would be better to remove this caveat from the two bullets in which it appears, and put it into the stem, such that the last main bullet reads, “Patient exhibits aberrant drug-related behaviors, including the following. Before acting on these, ensure that they are not the result of inadequately controlled pain.”

- **Reporting patients to law enforcement**: On page 18, the states, “Physicians have an ethical duty to report patients who are obviously diverting drugs to their local DEA office or their local police department.” As written, this language suggests that patients are diverting drugs to the DEA or local police. The sentence needs to be restructured to indicate that the report needs to be made to the DEA or police.
I also have a number of typographical and grammatical changes to suggest, but will send these separately. I hope that you find these comments helpful, and I would be happy to discuss them further with the appropriate people, if desired.

Sincerely yours,

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