Agenda Item 3

Comments on 2nd Draft California Prescribing Guidelines

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This paper addresses the circulated second draft of an updated guideline on prescription of controlled substances in California. This input is offered in response to a circulated invitation to attend an Interested Parties Meeting on November 15, 2022. Several aspects of the following paper are updated from a joint commentary submitted by the author and Dr Stephen E Nadeau, in June 2022. Joint comments with Dr Nadeau that apply in the second draft are incorporated with minor editing.

The present author is a healthcare writer and non-physician subject matter expert on public policy for the regulation of opioid pain relievers and clinicians who employ them in managing severe chronic pain. He has 26 years' experience as a patient advocate and forum moderator for online chronic pain communities, with over 150 published papers, articles and interviews in a mixture of mainstream medical journals, mass media, and Internet podcast venues.

This paper has greatly benefitted from earlier collaboration with Stephen E Nadeau MD. Doctor Nadeau has been a member of the faculty of the University of Florida College of Medicine since 1987, providing clinical care, teaching residents and medical students, and pursuing research, primarily in behavioral neurology, neuroplasticity, and neurorehabilitation. Since 2013, he has been Associate Chief of Staff for Research at Malcom Randal VA Medical Center. Opinions expressed in this paper may not reflect positions of the US Veterans Administration. Any newly introduced errors in the present paper are solely those of the primary author, Richard A Lawhern PhD.

Recent Events

This paper and to a considerable degree, the updated 2nd draft California Guidelines, reflect significant and ongoing changes in the regulatory environment for use of controlled substances in treatment of severe pain in America. Several key events have occurred during 2022, and should be explicitly acknowledged in the California Guidelines before they are reissued:

1. The American Medical Association released extensive comments in April concerning the February 2022 draft CDC opioid prescribing guidelines. These comments call into question much of the so-called "research" that CDC has referenced in its continuing and unjustified effort to suppress the use of prescription opioid pain relievers.

2. The US Supreme Court handed down a unanimous decision in *Ruan vs. the United States* in June 2022. This decision establishes that no clinician may be convicted of a crime solely because they employ prescription opioid pain relievers in managing their patients' pain. Prosecutors must establish that an accused has prescribed substantially outside accepted clinical practice and that they knew they were doing so at the time. This decision adds weight to multiple independent findings in County and State courts that prescription opioid medications do not comprise a "public nuisance" on the part of pharmaceutical manufacturers.

3. A landmark re-analysis of CDC data on opioid-related hospital admissions and opioid overdose related mortality was published in a mainstream medical journal on August 4, 2022. [see Aubry and Carr, *Frontiers in Pain Research,* Overdose, opioid treatment admissions and prescription opioid pain reliever relationships: United States, 2010–2019.] This analysis establishes that there is no cause-and-effect relationship between rates of opioid prescribing versus either hospital admissions for opioid toxicity or opioid-involved overdose mortality – and there has been no relationship since 2010. This reality appears to have been deliberately ignored by the writers of the 2022 CDC opioid guidelines.

   The Aubry/Carr paper is now one of the most widely read in peer-reviewed medical literature, with nearly 80,000 viewings in three months since publication. In the aulthor's view, the paper should be analyzed and explicitly reviewed in depth in any published California guideline for prescription of controlled substances.

4. Independent analysis of the publications records of authors selected to write the CDC guidelines reveals multiple unacknowledged conflicts of interest among those authors – conflicts that were known or should have been known to the CDC before initiation of guideline research in 2014 and 2020. Such conflicts establish a persistent pattern of anti-opioid bias that substantially compromises the integrity of the entire process used by US CDC in developing its prescribing guidelines.

   See Kollas, Schectman and Judy, September 2022, Undisclosed Conflicts of Interest by Physicians Creating the CDC Opioid Prescribing Guidelines: Bad Faith or Incompetence? ~ Pallimed

   and

   Kollas, Schechtman, Lewis and Judy, September 2022, Roger Chou's

Undisclosed Conflicts of Interest: How the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain Lost Its Clinical and Professional Integrity ~ Pallimed

5. In early November, 2022, US CDC published a "final draft" of a greatly expanded practice guideline for prescription of opioid pain relievers in acute, sub-acute and chronic pain. This document substantially doubles down on a record of profound errors and policy misdirection that has effectively wrecked the practice of pain management in America – and to which the California Guidelines have a significant potential to add damage.

   Fair disclosure: the author has summarized the 2022 CDC guideline in the following terms, in postings seen widely in social media:

   "Despite some conciliatory wording, the November 2022 CDC practice guidelines on prescription of opioids remain fatally flawed on both basic science and medical ethics. The document profoundly over-hypes asserted "risks" of opioid prescribing. It relies on weak medical evidence, cherry-picked research and outright junk science in 12 "recommendations" that will predictably drive even more clinicians out of pain management and more patients into suicide or street drugs. We now know there is no cause-and-effect relationship between rates of opioid prescribing and either hospital admissions or overdose-related mortality. Data published by CDC itself demonstrate no relationship since 2010. "Over-prescribing" is a mythology. But none of these realities are even examined by the CDC."

   This view is shared by many other subject matter experts who have published frequent criticisms of all versions of the CDC guidelines. Among those critiques is the following from Dr Jeff Singer, a Senior Fellow at the Cato Institute:

   The CDC Replaces Flawed 2016 Opioid Prescribing Guideline with a Flawed 2022 Opioid Prescribing Guideline | Cato at Liberty Blog

6. Multiple US States have recently passed legislation to substantially acknowledge harms done by public policy restricting availability of not only opioid therapy but any and all measures of pain management for medical patients. A key element of this legislation is requiring agencies of law enforcement to provide a court warrant demonstrating probable cause to believe that a crime has been committed, before being granted access to patient or clinician records in State Prescription Drug Monitoring programs. It is essential that California guidelines

provide similar protections and that the California Medical Board advocate for necessary changes to State laws.

The Central Role of "Risk" in California Guidelines

As the author of this paper has previously noted in comments submitted to the June Stakeholder Meeting, the term "risks" appears over 100 times in this 30-page document, and is referenced directly to the 2016 CDC opioid guidelines. Unfortunately, many uses of the term in the California guidelines are largely not germane to actual medical practice. Likewise, the so-called "crisis" that those guidelines were advertised as attempting to solve, has proven to be grossly mis-characterized. An Appendix to the present paper offers an alternative understanding of the true dimensions of America's public health crisis in substance abuse, alcoholism, and hopelessness.

The rising tide of opioid-associated deaths overwhelmingly reflects unsupervised use of opioids obtained on the illicit market, not exposure to prescribed analgesics. The underlying assumption of this draft guideline seems to be the idea -- never expressly stated -- that any patient prescribed opioids in the context of good care, and presently cognitively sharp and fully conversational, might be in imminent danger of keeling over any minute in respiratory failure. This construction is patently ludicrous.

Hugely unacknowledged in the CDC opioid guidelines and the derivative second draft California document is the reality that significant numbers of chronic pain patients are maintained on stab le doses of opioids for years with no evidence of substance abuse.

Reference: Forest Tennant, MD, DrPH, "Opioid Treatment 10-year Longevity Survey Final Report" *Practical Pain Management* December 20, 2011. https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/opioid-treatment-10-year-longevity-survey-final-report

Moreover, nowhere do I find an admission in this document that was deeply buried in the February 2022 draft update to the CDC guidelines:

> "The clinical evidence reviews found no instrument with high accuracy for predicting opioid related harms such as overdose or opioid use disorder (Chou et al., April 2020). It can be very challenging for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients.."

November 2022 CDC guidelines have deleted this phrasing and added discussion of several risk profiling instruments. However, careful reading reveals that the medical evidence for such instruments is weak, and their potential for misuse is remarkably high.

We see widespread reports in social media that risk profiling instruments such as NarxScore ™ have caused deep harms to some patients. Females with a history of childhood sexual abuse are particularly at risk for being denied pain therapy due to artificially inflated “risk scores”.

As I wrote with Dr Stephen E Nadeau in June 2022, the notion that clinicians must carefully evaluate individual patient risks versus benefits at every turn may reasonably be characterized as an oxymoron, in the absence of reliable instruments for doing so in a defensible manner. This conflict between reality versus theory must inevitably exercise a powerful chilling effect on the willingness of clinicians to risk Medical Board sanctions or law enforcement persecution in order to treat their patients.

Thus I must suggest that the Medical Board needs to embrace substantial further changes to their proposed Guidelines before final publication. Prescription opioid therapy presently plays an indispensable role in management of severe pain, both acute and chronic. Likewise, deep analysis of medical literature convinces me that the real “risks” of addiction or substance abuse attending such therapy are so low – and confounding factors in various investigators’ observations of outcomes are so numerous – that actual levels of risk for substance abuse in medical patients are too low to be accurately quantified.

From this background, I must again suggest that the emphasis on risk in the California prescribing guidelines is grossly over-hyped, reflecting many fundamental and fatal flaws in development of the CDC document to which the California guideline is closely related.

I again offer two deeply researched references in evidence of this misdirection.

Ref 1: Stephen E Nadeau MD, Jeffrey K Wu, and Richard A Lawhern, Ph.D. “Opioids and Chronic Pain -- An Analytic Review of the Clinical Literature”, *Frontiers in Pain Research,* August 17, 2021, Front. Pain Res., 17 August 2021, Citation https://doi.org/10.3389/fpain.2021.721357

https://www.frontiersin.org/articles/10.3389/fpain.2021.721357/full

In the 15 months since publication of this reference, it has been viewed over 43,000 times and cited 15 times in medical literature – a record of visibility that is rare for papers published in peer reviewed journals.

Also pertinent:

Ref 2: Stephen E Nadeau, MD, and Richard A Lawhern, PhD. “Management of Chronic Non-Cancer Pain – A Framework”, *Future Medicine (Pain Management)* June 1, 2022, https://www.futuremedicine.com/doi/pdf/10.2217/pmt-2022-0017

Unless the California guidelines are to be outright repudiated and withdrawn, I suggest that the second draft should be subjected to an independent “expert red team review” and significant additional rewriting before publication. I also urge the insertion of explicit literature references for each of the claims of fact made in the guidelines.

What is needed now in the California guidelines for prescription of controlled substances is a brief, focused, well organized statement defining a standard of practice that will protect clinicians and support staff from unjustified legal persecution or arbitrary Medical Board sanctions for “over-prescribing” within their individual understanding of the medical needs and circumstances of each patient. Ideally, this practice standard should not impose documentation requirements on clinicians, or testing requirements on patients that add to their shared workload, time burdens or fearful stress.

========= Specific Comments by Section =====

Preamble:

The revised preamble of the California guideline provides an extended discussion of the harms done by both the 2016 CDC guidelines and the California Death Certificate Project. Among other statements is the following:

> “In 2016, the Centers for Disease Control and Prevention (CDC) released guidelines for primary care providers which included recommendations for opioid prescribing for the treatment of chronic pain in outpatient settings. The goal of the CDC guidelines was to ensure that clinicians considered safer and more effective pain treatment prior to starting chronic opioid therapy in order to improve patient outcomes (i.e., reduced pain and improved function). Further, once opioids were prescribed, the goal was to encourage best practices to reduce the number of patients who go on to develop opioid use disorder, overdose, or experience other prescription opioid-related adverse events.”

As noted in the summary of current events above, we now understand that very few patients under medical supervision ever “go on to develop opioid use disorder”. Based on the work of Aubry and Carr, it has been demonstrated that there is no “epidemic” and little relationship between prescribing and adverse events. Moreover, US CDC is fully aware of this contradiction and has chosen to ignore it. The California Medical Board simply cannot reinforce such ignorance under any reasonable understanding of medical ethics.

As a consequence of published CDC data, it is impossible to reliably attribute opioid overdose mortality to medical treatment of the most frequently encountered patients.

The phenomena of addiction are far more complex than a purely “brain disease” model can account for.

Understanding Pain Terminology:

A definition should be added for Palliative Care (excluded from the CDC Guidelines)

Palliative Care is discussed by the American Academy of Hospice and Palliative Medicine in the following terms:

> “Palliative care is for people of any age and at any stage in an illness, whether that illness is curable, chronic, or life-threatening.” *Palliative care* is the relieving or soothing of symptoms of a disease or disorder while maintaining the highest possible quality of life for patients.”
>
> “Many people mistakenly believe you receive palliative care only when you can’t be cured. Actually, palliative medicine can be provided by one doctor while other doctors work with you to try to cure your illness.”
>
> “Palliative care may actually help you recover from your illness by relieving symptoms—such as pain, anxiety, or loss of appetite—as you undergo sometimes-difficult medical treatments or procedures, such as surgery or chemotherapy.”

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It is perhaps ironic that under this definition, all chronic pain management care may be considered “palliative” in the sense that it is directed to ameliorating symptoms even with limited expectations of permanent cure. Yet palliative care is explicitly excluded from 2022 CDC guidelines.

Reference: American Academy of Hospice and Palliative Medicine, https://palliativedoctors.org/palliative/care. Credit for research discovery: Kat Hatziavramidis, Esq, Chicago IL

Recommended Practices:

This section of the second draft states that

> “Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of medication assisted therapy such as Methadone and Buprenorphine. For some physicians, there may be advantages to becoming eligible to treat opioid use disorder using office-based buprenorphine treatment. Referral to a pain medicine specialist or addiction medicine specialist prior to initiation of opioid therapy in high-risk patients may be considered as part of a risk mitigation strategy.”

Author Observations: the practice of pain management in chronic patients is inherently highly complex and time consuming. Treatment of chronic pain requires extensive education and experience, even as there is presently an incredible paucity of such training. [Ref 3]

Conditions of practice in addiction treatment are equally challenging. It is a fundamental error to presume that patients can simply be put on Buprenorphrine or Methadone (even as useful as these medications are) without also examining the many psycho-social-economic issues that frequently surround addiction – e.g. mental health issues, poor education, unemployment, homelessness, co-morbid alcoholism etc. Thus the practicality of dual practice in pain management and addiction treatment is highly debatable.

In too many cases, specialists in both of these fields have been driven out of practice by excessively zealous regulation and law enforcement. Thus, it may be necessary for the State Medical Board to advocate for a funded long-term and multi-dimensional program to bring clinicians back into both fields, and to "grow" the numbers of interns and Residents who initially choose these fields of specialty. Failing such initiatives, the current severe doctor shortage will only worsen, resulting in even more patient desertions.

Ref 3: Shipton EE, Bate F, Garrick R, Skeketee C, Shipton EA, Visser EJ. "Systematic review of pain medicine content, teaching, and assessment in medical school curricula internationally." *Pain Therapy.* 2018;7:139-61.

Exploring Non-Opioid Options:

This section includes the following:

> "Opioid medications should not be the first line of treatment for a patient with chronic non- cancer pain. Other measures, such as non-opioid analgesics, non-steroidal anti- inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non- pharmacologic therapies (e.g., physical therapy, pain psychology, nerve block, joint injections), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. Determining if potential benefits of opioid analgesics outweigh the potential risks is key."

Author Observations: While each of the named pain therapies may have a role in long term treatment of chronic pain, there is little or no clinical evidence that they are

"preferable" when pain is severe. NSAIDs at high doses have their own hazards in hundreds of yearly hospital admissions for intestinal bleeding and toxic liver reactions. Anti-epileptic drugs and anti-depressants apply primarily in neuropathic pain, and often cease to provide pain relief after months or years of success. Physical therapy is often impossible for patients until their pain is first at least partially controlled by other means. Pain psychology has never undergone large scale trials as a substitute for opioids.

As mentioned previously, there are no reliable patient profiling instruments for predicting individual risks of negative outcomes. Thus non-opioid pain therapies are presently best characterized as initial therapy for light to moderate pain, but may not be practical as primary long -term therapy in severe pain. Non-analgesic therapies are most certainly not "replacements" or in any demonstrated sense "preferable" to opioids.

Ref 4: Richard A Lawhern and Stephen E Nadeau, "Behind the AHRQ Report -- Understanding the limitations of "non-pharmacological, non-invasive" therapies for chronic pain." *Practical Pain Management,* Vol 18 #7, October 3, 2018, https://www.practicalpainmanagement.com/resources/practice-management/behind-ahrq-report

Also of concern for this section is that there is at least a fifteen-to-one variation in minimum effective opioid dose, as reported in medical literature. A significant part of this variability may be due to natural genetic polymorphism in expression of six key liver enzymes that govern metabolism of many medications in the liver. [op cit Ref 3]. Tellingly, the draft California Guideline document fails even to mention the terms "genetic" or "genomic". This omission should be constructively addressed in detail.

Morphine Milligram Equivalent Dose

This section currently reads as follows:

> "Some clinicians have questioned the conceptual validity of MME because there is a lack of consensus regarding a universally accepted opioid-conversion method for patients taking opioids chronically. Despite these concerns, calculating the total daily dose of opioids can be useful in identifying patients who may benefit from closer monitoring, reduction or tapering of opioids, being offered a prescription for naloxone, or other measures to reduce risk of overdose. The CDC has developed a fact sheet titled Calculating Total Daily Dose of Opioids that provides one method for calculating a daily dose of opioids. The selection of an opioid dosage for a patient is a clinical decision made on a case-by-case basis in order to provide an individualized, patient-centered treatment plan. The risk to a patient increases as dosages increase and the rationale for the decision to prescribe a dosage ≥ 90 MMEs should be documented in the patient's medical record. California law requires that a prescription for naloxone be offered to a patient when the dosage [is] ≥ 90 MMEs"

Author Observations: The Opioid Workgroup of the Board of Scientific Advisors to the US National Centers for Injury Prevention and Control directly challenged the 50/90 MMED thresholds of both the 2016 CDC guidelines and proposed revised and expanded 2022 draft guidelines, as lacking any scientific basis. No less an authority than the American Medical Association has also publicly stated that many patients are well served by opioid dose levels exceeding 90 MMED. [Ref 6] There are case reports of a few patients who function well on doses exceeding 2,000 MMED, without impairment of cognitive function and with significant improvements in quality of life.

In the view of large numbers of clinicians, the concept of "Morphine Milligram Equivalence" is unsupported in the medical literature, and may properly be characterized as junk science. [Ref 4A].

All references to numerical MME dose thresholds or treatment time limits should be removed from the California Guidelines. This action is also consistent with the most recent edition of opioid guidelines issued by the Federation of State Medical Boards.

To the extent that California law levies MME limits on medical practice, such laws must be repealed as destructive to the practice of medicine and the welfare of patients. The California Guideline on Prescription of Controlled Substances should explicitly advocate to this end.

Ref 4A: Jeffrey Fudin, Jacqueline Pratt Cleary, Michael E Schatman "The MEDD myth: the impact of pseudoscience on pain research and prescribing-guideline development", *Journal of Pain Research,* March 4, 2016, https://www.dovepress.com/the-medd-myth-the-impact-of-pseudoscience-on-pain-research-and-prescri-peer-reviewed-fulltext-article-JPR

Ref 5: Dr Chinzano Cunningham, "Observations of the Opioid Workgroup of the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids", July 16, 2021 https://www.cdc.gov/injury/pdfs/bsc/Observations-on-the-Updated-CDC-Guideline-for-Prescribing-6-30-2021-508.pdf

Ref 6: Interim Meeting of the House of Delegates, American Medical Association, "Resolution 235, -- Inappropriate Use of CDC Gujidelines for Prescribing Opioids" November 13, 2018.

Counseling Patients on Overdose Risk and Response

This section of the California Guidelines mandates offering prescriptions of Naloxone to any patient receiving more than 90 MME per day of an opioid medication.

Author Observations: As noted previously, the 90 MMED threshold proposed in this section is arbitrary and unsupported by trials data of any kind. Likewise, while Naloxone has been used effectively as an intervention by first responders with addicted (often socially isolated) persons who overdose on illegal street drugs, there is no body of evidence that even remotely supports general utility of this intervention in pain patients who are under active medical oversight, and who have support from co-resident family members. At least one controlled randomized trial in a clinical pain population failed to reveal any benefit.

Ref 6A: Banta-Green C, Coffin PO, Merrill JO et al. "Impacts of an opioid overdose prevention intervention delivered subsequent to acute care." *Injury Prevention.* 25(3), 191–198 (2019).

Although many persons with addiction suffer from chronic pain, the opposite is rarely the case. Emergence of substance abuse or addiction in medically managed patients is in fact rare even in patients assessed to have background factors associated with increased risk of substance abuse. [Ref 7]

The typical chronic pain patient is a female in her 40's or older. If her life is stable enough to allow her to see a physician regularly, she is very unlikely to suffer from a substance use disorder. However, the typical addict is a young adult male with a high school education, a history of unemployment and mental health issues, and possibly involvement with law enforcement. It is well known that this population is medically underserved.

Incidence of prescription opioid overdose in medical patients appears to be on the order of 0.25% to 0.5% per year – too small to reliably identify any sub-group of patients under treatment which may actually benefit from naloxone prescriptions. [op cit Ref 2 and Ref 6B]

Ref 6B: Bohnert ASB, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, et al. "Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA.* (2011) 305:1315–21. doi: 10.1001/jama.2011.370"

Ref 7: Nora D Volkow, MD, and Thomas A McLellan, Ph.D., "Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies" . *NEMJ* 2016; 374:1253-1263 March 31, 2016]. http://www.nejm.org/doi/full/10.1056/NEJMra1507771

Ongoing Patient Assessment

Author Observations: The medical literature offers no hard data on benefits of urine testing for patients themselves. [op cit Ref 2, Ref 3] Many clinicians are also not appropriately trained on interpretation of urine test results, and many insurance plans do

not reimburse for such testing. [Ref 8] Arguably the only real reason for such testing is to provide the doctor with an excuse for discharging non-compliant patients – a practice profoundly not in the patient's best interests and potentially comprising patient desertion.

Ongoing patient assessment is clearly appropriate and needed -- but not for the reasons or following from the logic offered in the draft California guideline.

Ref 8: Utsha G Katri and Shoshana V Aronovitz "Considering the harms of our habits: The reflexive urine drug screen in opioid use disorder treatment" *Journal of Substance Abuse Treatment,* April 2021. https://doi.org/10.1016/j.jsat.2020.108258

Compliance Monitoring

Author Observations: There are no hard data in medical literature to establish patient benefits from treatment contracts [Ref 8A]. The real motivation behind this section is quite obvious: to provide excuses for patient discharge or involuntary tapering – both of which are associated with significantly increased incidence of medical crisis and/or patient overdose mortality. [Ref 9]

This section of the California Guidelines should be rewritten to make clear that patient drug-seeking behavior is in fact rare. Greater focus is needed on assessing blood plasma levels of prodrugs (metabolic products) generated by opioid therapy, as an aid to adjusting dose levels to the metabolism of the individual patient.

Ref 8A: Roger Chriss, "Little Evidence that Pain Contracts Work", *Pain News Network,* March 21, 2017. https://www.painnewsnetwork.org/stories/2017/3/21/little-evidence-that-pain-contracts-work

Ref 9: Alicia Agnoli , Guibo Xing , Daniel J Tancredi , et al: "Association of Dose Tapering With Overdose or Mental Health Crisis Among Patients Prescribed Long-term Opioids" *Journal of the American Medical Association,* August 3, 2021, doi: 10.1001/jama.2021.11013 https://pubmed.ncbi.nlm.nih.gov/34342618/

Pill Counting

Author Observation: Pill counting communicates a profound message of distrust between clinicians and patients, compromising the doctor-patient relationship and stressing the patient. The desired objective is better supported by the clinician entering case file notes when patients present with requests for early renewal or increased dose levels, and/or repeated reports of lost or stolen medications.

CURES Reports -- also **Urine Drug Testing**

Author Observations: Law enforcement access to the CURES database should be conditioned upon issuance of a court warrant establishing that there is probable cause to believe a crime has been committed. Nineteen other US States have already taken action to guarantee such legal due process for clinicians and their patients. [Ref 10] The California Medical Board should explicitly endorse this change to California law in its opioid guidelines. Likewise, remove reference to CDC "fact sheets" on this subject, as the CDC material is riddled with errors and anti-opioid bias.

[Ref 10]: Jeffrey A Singer, "Arizona Becomes 19th State to Ban Warrantless Searches of Prescription Drug Database" *Cato At Liberty,* June 16, 2022. https://www.cato.org/blog/arizona-becomes-19th-state-ban-warrantless-searches-prescription-drug-database?

Tapering and Discontinuing Opioid Therapy

This section includes the following reasons for discontinuing or tapering opioids:

> "Patient has been treated with opioids for a prolonged period (e.g., years) and current benefit-risk balance is unclear
>
> "Patients with unanticipated challenges to tapering, such as inability to make progress in tapering despite opioid-related harm, might have undiagnosed opioid use disorder."

Author Observations: If the current benefit-risk balance is "unclear" to the clinician, then additional interview and characterization of patient's quality of life are indicated. Patient dismissal or forced tapering are tantamount to doctor desertion.

It is likewise far more likely that patient challenges are a consequence of uncontrolled breakthrough pain, possibly complicated by clinician predispositions to misinterpret their distress and depression as "drug seeking behavior". This phenomenon is properly referred to as "pseudo addiction" and should be explicitly discussed as such in this section of the California guidelines.

While referral for co-treatment of drug addiction or substance use disorder is sometimes appropriate in a small cohort of patients, a decision to terminate care for chronic pain solely for the protection of the clinician from censure is never under any circumstances medically ethical.

[Op cit, Ref 2]

Terminating Care

Author Observations: In the current draconian regulatory environment, pain management clinicians are leaving practice in large numbers, fearful of Medical Board

or law enforcement sanctions, burnt out by ever increasing patient loads. Thirty days notice of termination is completely inadequate and potentially dangerous to patient survival. Among chronic pain patients under care with opioid medications – even those identified as substance abusers – it is medically unethical to discharge a patient in the absence of a transition plan to a qualified and licensed provider.

Special Patient Populations

This section of the California Guidelines identifies populations in which the Guidelines may not apply. Specifically excluded are acute pain, cancer pain and end-of-life pain. Special cautions and conditions are applied to clinician decision making in Emergency Department treatment of acute pain.

Specifically in the context of Emergency Departments, the statement is made:

> "… anticipated risks and benefits along with alternatives should be discussed with the patient. If deemed appropriate, only low-dose, short-acting opioids with a short duration of therapy should be prescribed."

Likewise, the Guideline offers a link in this section to an external document: "Safe Pain Medicine Prescribing in Emergency Departments and Urgent Care Centers"

Author Observations: In all clinical settings, the appropriate objectives for pain treatment are promotion of full healing and independent life, alleviation of suffering and promotion of patient quality of life – in each case, "to the extent possible." There should be no ethical distinction in principle between treatment of cancer-related pain versus non-cancer pain. These objectives need to be explicitly acknowledged in the Preamble and appropriate subsections of the California Guidelines.

Both immediate-release and long-acting opioid analgesics have roles to play in all types of pain treatment. Long-acting opioids may have the advantage of being more regularly scheduled, promoting better overnight rest. They are also less prone to accidental overdose after the patient is discharged, once the patient's sensitivity to medication is established during hospital admission and medication response monitoring.

A deep reading of the "Safe Pain Medicine Prescribing" document reveals a remarkable lack of rigor in its assertions, and close connections to the 2016 CDC prescribing guidelines. In light of the recent publications noted in the initial section on "Current Events" above, this link should be removed from the California Guidelines.

Mention is also appropriate in this section of training patients to use a medication dispenser and a daily schedule checklist to ensure regular dosing. [op cit Ref 3]

Older Adults and **Pediatric Patients**

Authors' Observations: As in previous sections, all references to 90 MME thresholds should be removed. Likewise, explicit recognition is in order for the low and historically stable rates of opioid overdose related mortality in older adults and pediatric patients, as compared with adults 25-60. Also needed is acknowledgement that literally millions of Seniors are effectively managed on opioid doses exceeding 100 MME per day – and Centers for Medicare Services so-called "Over-Utilization" tools have a poor record of predicting hospital admissions for drug toxicity or overdose in this population. [Ref 11]

[Ref 11] Yu-Jung Jenny Wei, PhD; Cheng Chen, BSPharm; Amir Sarayani, PharmD; et al "Performance of the Centers for Medicare & Medicaid Services' Opioid Overutilization Criteria for Classifying Opioid Use Disorder or Overdose *JAMA*. 2019;321(6):609-611. doi:10.1001/jama.2018.20404
https://jamanetwork.com/journals/jama/article-abstract/2724180

Reasons for FDA safety labeling on codeine in cough medicines for children should be made explicit and discussed in detail. The FDA safety alert was generated because of concerns for hyper-metabolism in generating high concentrations of prodrug components (morphine) that cross the blood-brain barrier.

Author's Concluding Remarks

Opioid analgesic medications have a 2,000-year history in the alleviation or management of pain. To imply that these medications are not safe and effective in such a purpose is simply ludicrous.

Despite giving lip service to the need for individualized patient treatment under evidence-based guidelines, the second draft of proposed "California Guidelines for Prescribing Controlled Substances for Pain " remains closely aligned to the 2016 and 2022 CDC Practice Guidelines for prescription of opioids to adults with chronic non-cancer pain. In the author's view, this alignment is a fundamental and fatal error.

It is now widely understood among clinicians that the CDC guidelines suffer from a pre-existing and deeply entrenched anti-opioid agenda, cherry picked and conflated research, disproportionate and unjustified emphasis on presumed but largely unproven "risks" versus benefits, an absence of validated instruments for assessing risk in individual patients, and from clear professional conflicts of interest among the CDC writers [see **"Recent Events"** above].

CDC guidelines have substantially injured and caused the desertion of millions of people in pain. California guidelines as proposed in second draft have the potential for continuing that damage for State residents.

As long as the proposed California Guidelines remain aligned with CDC, they will continue to be used as an excuse for law enforcement to arbitrarily persecute doctors out of practice and sometimes to imprison them for doing no wrong other than treating pain patients with the most effective means. The Board may also find itself increasingly isolated from patient communities that simply do not believe its good will. It is therefore imperative that the California Medical Board divorce itself and the State from CDC misdirection.

Fortunately, there are other frameworks from which prescribing guidelines may be written. One such framework is outlined in great detail in [Ref 3]. Another is of longer standing. The World Health Organization Analgesic Ladder was first published in 1986 and has since been generalized beyond cancer pain [Ref 12]. This framework is taught in medical schools. It has also been the subject of ongoing efforts to integrate recently emerging applications of so-called "interventional" pain therapies within its framework.

My previous comments to the June 2022 Interested Parties Meeting, co-authored with Dr Stephen E Nadeau, include a translation of the WHO Analgesic Ladder into 12 recommendations paralleling and correcting those of the CDC guidelines. This material is not advocated as a final product or "standard", but rather as a point of departure for California Medical Board reconsideration and refinement of the logic, goals and definitive medical evidence pertaining to treatment of pain.

Ref 12 Aabha A., Anekar; Marco Cascella., "WHO Analgesic Ladder" , available full text at the US National Library of Medicine:
https://www.ncbi.nlm.nih.gov/books/NBK554435/

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Treatment of pain employing opioid analgesics is almost universally understood among practicing clinicians to involve the following measures:

Start with medications and minimum dose levels expected to be effective for the sources and severity of pain.

Titrate up opioids (when employed) to desired effect, monitoring for and managing undesired side effects (constipation, nausea, sleepiness, slowed reaction time, cognitive confusion or distortions).

Consider changing medication type or dose if pain remains refractory or side effects become unacceptable to the patient.

Monitor for development of medication tolerance.

Aggressively monitor for and treat depression or anxiety, with awareness of potential drug interactions.

Supplement analgesic treatment with adjudivant treatments or counseling support where available.

Actively engage family or community caregivers in a treatment and support team.

Taper medication down gradually as patient conditions improve or if the patient requests, again monitoring for and managing unacceptable effects. Reversal of trial tapers is entirely appropriate if the patient experiences high levels of breakthrough pain.

___ ___ ___

Appendix: "The Opioid Crisis on One Page"

An early version of this summary of the opioid crisis has been posted widely on social media. With expansion of text fonts and addition of points suggested by chronic pain communities, it is now slightly over one page in length.

--- --- ---

- **US "War on Drugs" began 50 years ago under the Nixon administration**
- **2000-2010** - a few doctors and pharmacists operated pill mills contributing to the drug crisis
- **2010-2012** – Prescription Drug Monitoring Programs and DEA crackdown mostly suppressed pill mills. **Prescribing began to fall.**
- **Since 2010** the **opioid crisis** is **<u>un</u>related to *so-called* "overprescribing"** by doctors
  - ✓ **No** current **relationship between** opioid prescribing, hospital admissions or overdose mortality As prescribing has fallen dramatically (more than 44%) deaths from overdoses have more than tripled
  - ✓ Opioid crisis is dominated by illegal street Fentanyl, Heroin, Meth and alcohol
  - ✓ Likely **fewer than 3%** of **medical patients** later **develop substance abuse**
- **Present** – There **is** still a genuine "opioid crisis" in addiction, hospital admissions and deaths due to **counterfeit drugs** contaminated with **illegal fentanyl**

US CDC got their story wrong TWICE – first in 2016 and now 2022!

- 2016 CDC opioid guidelines, and the recent February 2022 expanded draft, over-emphasized risk and ignored benefits of opioid therapy
- Recommendations are based on weak and cherry-picked research, conflated, or misinterpreted findings
- Ignored well-documented **wide range of individual opioid metabolism re: minimum effective dose** in favor of arbitrary maximum caps, ignoring research, clinician and pain specialist input
- Tried to replace opioid therapy with "alternatives" that do NOT work for many patients
- Writing team had unacknowledged conflicts of interest and anti-opioid political agenda

Results of bad "guidance"

- Real crisis is from social determinants of health - a crisis of hopelessness
  Pain specialists are fleeing the profession and many physicians refuse to treat pain patients
- Currently, within the chronic pain community, there is crisis of under-treated pain leading to loss of income and productivity, severe drops in quality of life, and increased suicide

What must be done now?

- Publicly and prominently **repudiate** and **withdraw** the 2016 and 2022 CDC guidelines
- Actively lobby US states and DEA to repeal "guidelines"- based law and practice standards
- Delegate development of practice standards to practicing clinicians in specialty academies

Alternately and/or concurrently

- Start over with unbiased writers and review teams, including clinicians in community practice, patients and their advocates

Richard "Red" A. Lawhern, PhD, November 2022

FROM: AGNES LEON
SENT: Tuesday, November 8, 2022, 8:49PM
TO: CADY, SUSAN@MBC.CA.GOV
SUBJECT: Interested Parties Meeting: Prescribing Guidelines, comments.

1. Preamble: Paragraph 4, Please consider removing the word “INADVERTENTLY ” contributed to patient harms due to underrated pain”.

Here is why I feel this way. In 2016 the CDC was warned about the extreme patient harms that would result as a result of these (unethical) “Guidelines“. The CDC was well aware that restrictive "regulatory” pressure would likely result and in turn harm vulnerable patients. Yet the CDC chose to plow ahead. Then, the CDC waited SEVEN long years, despite verifiable patient “harms”, including suicides, escalating street drug OD’s, patient medical collapse, etc., before issuing more draconian “guidelines’”. At this point I would argue that “intended consequences” of patient harms, would be more descriptive of CDC public policy. So please eliminate ‘Inadvertently' completely and replace it with nothing.

2. RE: Page 21 Inherited Legacy Patients.
It seems almost impossible to find opiate friendly doctors (or N.P. 's) who I can transition care to. Without references patients are left “shooting in the dark”. A very dangerous place indeed.

Does the CA Medical Board have a help organization or a list of referrals with open practices for patients in dire need? How can the CMB help the many patients who presently require new pain management MD’s. Many patients require opiates to function and lower their pain level but can’t find practitioners.

2. What are the CMB impressions of the November 3, 2022 CDC OGL? As a result of the 2016 CDC “Guidelines”, many patients have suffered severe 'disruptions in care', physical and emotional harm, and abandonment from doctors due to “regulatory pressure”.

How do you see the 2022 CDC GL impacting pain care in California? How will the CMB encourage doctors to prescribe and encourage individualized care with regard to opiates?

Do you see a future DEA 50 MME cap in Opioid treatment for chronic pain? I see no metric cap numbers in the CMB proposed draft. What if the DEA continually exerts their heavy hand and “harms”(kills) more patients by forced tapers? What is your plan to protect vulnerable patients, and their doctors, who follow the CMB guidelines and prescribe above 50 to 90 MME? Without CMB standing up to the DOJ the hard work you have done will fail. We are at war with our federal government for the lives of our patients. Which will prevail?

Last thought:

Excerpt from: The Truth About Chronic Pain, By A.Rosenfeld. 2003.

"…physicians are sworn to serve their patients, not judge them. Pain control is a patient right, not a patient privilege, and treating the pain patient properly and compassionately is the healer's job."

"Maybe the whole problem of inadequate pain management boils down to the intersection between cultural prejudice and medical education."

"It does. And the victim, as in all things in medicine, is always the patient. Not the drug companies, not the DEA, not the doctors, nurses, or pharmacists, but the patient. If anything goes wrong, it's always the patient that pays the price. And he pays the price big time in the pain game—perhaps the most tragic patient experience in American medicine today."

Thank you for all your hard work and dedication.

Please continue to advocate for the most vulnerable…. the patients. Please spread your guidelines to other states to help return humane pain care to the USA.

Retired RN, BSN
Pain patient and still very much a patient advocate.

From: Peggy
To: Susan.L.Cady@mbc.ca.gov;
Subject: CA OPIOID PRESCRIBING 2nd UPDATE DRAFT
COMMENTS/RECOMMENDATIONS

First, I'd like to thank the board for taking the time and making the effort to work with the interested parties. It is crucial that we protect doctors and patients from the harm that has come with over-regulation and I can see that the board is making an attempt to do that. While this document has improved in some areas since the last draft, I still have some serious concerns about this document.

There are several general problems right out of the gate that I have with the updated MBC and CDC opioid GLs.

Bias against Chronic Pain Patients on Long Term Opioid Therapy.

These guidelines are still presented in a biased manner that does not reflect the real benefits of long term opioid treatment in pain patients thus leading physicians down a path that stokes fear of prosecution and liability for patient addiction and/or death. This leads to unnecessary oversight that compromises the patient's sense of self. We know chronic pain patients rarely develop OUD yet they are treated as if they have it or will eventually develop it. This is not consistent with the science and speaks to the bias that continues to misdirect aid to the thousands of people dying from poisonous black market drugs. This bias against Rx drugs and pain patients creates a toxic patient/physician relationship and is detrimental to the health of the patient and to the practicing physician and has led to a complete collapse of the practice of pain management.

Today's nonmedical opioid users are not yesterday's patients...
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6369835/

Performance of the Centers for Medicare & Medicaid Services' Opioid Overutilization Criteria for Classifying Opioid Use Disorder or Overdose
https://jamanetwork.com/journals/jama/article-abstract/2724180

Of particular concern are the use of "risk prediction" tools that have not shown clinically to predict OUD. These affect women on a much greater scale and contribute to the disparities in health equity for women, particularly in the management of chronic pain and acute pain. There are millions of women who suffer from such conditions who benefited from pain medication and who no longer have access due to built in systems in the PDMP, possibly CURES, such as NarxCare as well as tools similar to the ones in this document. For example, there are countless stories of women in the online support groups being denied access to pain medication due to a history of sexual abuse and/or depression. These conditions do not seem to prevent access to pain meds for men. It's important that this guideline stresses that the data shows these tools are unable to predict absolute risk even those predisposed to OUD thus they should not be used to deny pain medication but rather as a guide for how to structure oversight of pain

medication use. Doctors have a priority to do what is best for the patient, full stop. They are not law enforcement and should not be forced to act like it. Given the totality of the circumstances (ie. data showing very low likelihood for addiction/death among chronic pain patients, patient abandonment due to over-regulation, suicides due to untreated/ undertreated pain, non-medical users poisoned by toxic amounts of illicitly manufactured drugs rather than Rx drugs, as well as the lack of evidence showing current recommendations improve patient outcomes) UDTs, pill counts, screening tools, etc. should not be used for chronic pain patients with no history of drug abuse.

The strong bias toward the use of such mitigation tactics is unwarranted and creates a tense and adversarial atmosphere from the start that further perpetuates the stigma against pain patients. Chronic pain patients are the least likely to divert their meds because they rely on them to function.

I'm not saying that caution isn't warranted. I'm only saying that people need to stop acting like everyone is going to become an addict if they take pain medication. It's simply not true and our medical system should not be hyper focussed on continuing to spread this false narrative as if this narrative has merit.

I just finished watching an FDA/NIH workshop regarding medical devices for opioid monitoring and risk prediction. One of the key take-aways is, while innovation is important, so too is stigma and accuracy. One of the panelists who was talking about genetic testing stressed the importance of targeting the right population. She pointed out that (paraphrasing) ‘someone who has already been exposed to opioids and is doing fine does not need the test to predict OUD’. The same should apply to the use of risk mitigation tools in chronic pain patients and others who have been exposed and done well. Patient history is key to creating an environment in which patients can trust and heal.

Weigh the risks and benefits, take precautions, but don't exaggerate the risks or devalue the benefits and for God's sake don't treat people like criminals in health care settings. There is absolutely no reason to withhold pain medication from someone who is suffering, and that includes those with use disorder. If this crisis has taught us anything, it's that withholding treatment causes far greater harm and death than any prescribed drug. We must keep in mind going forward that no mitigation tools can predict absolute risk and this board needs to protect doctors from regulators who dismiss this fact in favor of punishing doctors who examined the risks and concluded with the patient that the impact of untreated or under-treated pain, on the patient's body and mental health, irrespective of risk, was more dangerous to the overall health of the patient than the risk of misuse or OUD.

The following are specific changes I would like to see made:

Pg. 2 Preamble
---Add the text and the link below to the beginning of the preamble. You can put it elsewhere if you like but it should be highly visible to let clinicians know significant changes have been made to the way clinicians can be convicted :

"On July 7, 2022, the Supreme Court ruled (9 - 0) against the United States and in favor of physicians on what is necessary to convict clinicians:
Ruan v. United States, 20-1410. The Court held that once a doctor who is charged with dispensing controlled substances produces evidence that his conduct was "authorized," (meaning licensed to prescribe) the Government must prove beyond a reasonable doubt that the doctor knowingly or intentionally acted in an unauthorized manner."
https://www.supremecourt.gov/opinions/21pdf/20-1410_1an2.pdf

Pg. 3 - Understanding Pain Terminology
- I do think it's crucial to define palliative care and hospice care, especially since it talks about the two, the primary difference between the two being that death is not imminent in palliative care and curative treatment may continue. Many in the medical community confuse the terms and think they are the same. They are not the same and it is critical that clinicians understand the difference.

Please add the following definition:
"Palliative Care:
Palliative care helps people with serious illnesses feel better by preventing or treating symptoms and side effects of disease and treatment. The goal of palliative care is to help people with serious illnesses feel better. It prevents or treats symptoms and side effects of disease and treatment. Palliative care also treats emotional, social, practical, and spiritual problems that illnesses can bring up. When the person feels better in these areas, they have an improved quality of life.

Palliative care can be given at the same time as treatments meant to cure or treat the disease. Palliative care may be given when the illness is diagnosed, throughout treatment, during follow-up, and at the end of life.

Both palliative care and hospice care provide comfort. But palliative care can begin at diagnosis, and at the same time as treatment. Hospice care begins after treatment of the disease is stopped and when it is clear that the person is not going to survive the illness."
https://medlineplus.gov/ency/patientinstructions/000536.htm

Pg. 7 Assessment for Opioid Misuse Behavior
Current Text:
"Assessment of the patient's personal and family history of alcohol or drug use and relative risk for medication misuse must be part of the initial evaluation and ideally be completed prior to a decision to prescribe opioid analgesics. This can be done through a careful clinical interview, which also can inquire into any history of physical, emotional, or sexual abuse, as these have been correlated with substance misuse. Refer to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (or the current DSM version) for criteria for diagnosing Opioid Use Disorder."
--- Add: The presence of prior sexual, physical, or emotional abuse should not preclude opioid treatment.

Amended Text:
"Assessment of the patient's personal and family history of alcohol or drug use and relative risk for medication misuse must be part of the initial evaluation and ideally be completed prior to a decision to prescribe opioid analgesics. This can be done through a careful clinical interview, which also can inquire into any history of physical, emotional, or sexual abuse, as these have been correlated with substance misuse. The presence of prior sexual, physical, or emotional abuse should not preclude opioid treatment for pain. Refer to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (or the current DSM version) for criteria for diagnosing Opioid Use Disorder."

TAPS Mitigation tool: This tool says on the TAPS website:
"the TAPS Tool has adequate sensitivity (>70%) only for tobacco, alcohol, and marijuana."
--- I think the above statement should be added next to the TAPS link or deleted from this section, as clearly this is not useful for all patients.

Pg. 8 Patient Consent:
I have one concern with the link in this example. It is geared for people who are not permanently disabled. If this were used for someone not working, it would have to be modified. This can be as simple as lining out a few words but the need for modification should be noted.
--- Add:
"Forms should be modified to fit the patient's circumstances."

Pg. 9 - Pain Management Agreements
"Use of a pain management agreement is strongly recommended for patients when the opioid therapy is expected to require more than three months of opioids or when initiating an opioid trial for a chronic pain patient. Pain management agreements typically outline the joint responsibilities of the physician and the patient and should include:"
--- Strike the word "strongly" from the first sentence above.
For patients who are already on LTOT and doing well, pain management agreements are not necessary and, when added to the record, may stigmatize the patient and lead others who view the chart to falsely believe aberrant behavior has developed. This could be especially detrimental to patients whose charts are reviewed annually for disability purposes where such documentation could cause a knee-jerk reaction and lead to a loss of benefits and inability to get appropriate care. This is also why mitigation efforts such as mandatory UDTs, Pill Counts, etc. should not be used in a patient that has never had such tests and who does not show aberrant behavior. It is crucial that the board protect doctors who recognize they are treating legacy patients who are vulnerable to stigma, discrimination, and loss of benefits, and who might very well be unintentionally harmed by adding unnecessary and misleading documentation to the patient's medical record. Therefore, it is critical that such mitigation strategies not be required or strongly worded to imply there is no room for individual decision making.

Examples of pain agreements

--- Delete the first two links as they are very one-sided agreements that only protect the doctor, not the patient. Those first two are more appropriate for rehab clinics but still would need modification to protect the patient. The third link is okay as long as it is understood that the current opiophobia has created a climate wherein it is very difficult to get medication from one pharmacist, largely due to DEA production and distribution quotas that are creating shortages and fear of dispensing.

Pg. 10 - Initiating Opioid Trial
"Safer alternative treatments should be considered before initiating opioid therapy for chronic pain."
--- Strike the word "safer" and start with the word "Alternative".
Again, I believe the use of the word "safer" is not appropriate and actually contributes to patient harm. The "go-to" meds are acetaminophen and NSAIDS. Neither of those are safer alternatives for someone with moderate to severe pain, those taking arthritis medication or who suffer with liver, kidney, or heart disease, but that is the medication they are told to take because clinicians are wrongly led to believe it's "safer" than opioids. It is not appropriate to take these meds round-the-clock, seven days a week, 52 weeks a year and yet this is the option being given to many chronic pain patients. These drugs typically should not be used for more than three weeks. Acetaminophen says "do not use more than 10 days unless directed by a doctor". The problem is, doctors are told it is "safe" while hospital admissions from accidental OD and liver failure surge.

The number of chronic pain patients and even acute and subacute pain patients being told to take these medications on a daily basis is striking. Yes, Acetaminophen can be useful for mild intermittent pain but most chronic pain patients who require daily meds suffer from moderate to severe pain and there appears to be no distinctions from clinicians as to when these meds are and aren't appropriate. Rather, there is an inclination to dismiss the harmful effects of these drugs in order to avoid regulatory scrutiny for prescribing opioids. I cannot stress enough the massive doses patients are being told to take. This is particularly critical because the "safe" dose and the "toxic" dose are much closer than with other pain relievers, thus it is very easy to overdose and cause organ damage.

I'm not advocating these drugs not be used first, I'm simply saying they are definitely not "safer" for patients who require daily medications. Saying they are "safe" creates a narrative that leads everyone to dismiss the often lethal side-effects of these drugs. And, since they are OTC, clinicians often do not specify safe dosages or caution patients about side-effects and accidental overdose which can lead to liver failure as in the case of acetaminophen or ulcers, MI, and kidney failure in the case of NSAIDs. The available data suggest that acetaminophen and NSAID-related adverse events place a substantial clinical and economic burden on the healthcare system.
Acetaminophen Toxicity
https://www.ncbi.nlm.nih.gov/books/NBK441917/
Acetaminophen and the U.S. Acute Liver Failure
Study Group: lowering the risks of hepatic failure
https://pubmed.ncbi.nlm.nih.gov/15239078/
'Generally Safe' NSAIDs?

https://www.aafp.org/pubs/afp/issues/2001/0215/p637.html
Quantifying the Impact of NSAID-Associated Adverse Events
https://www.ajmc.com/view/a467_nov13_fine_s267
Is Tylenol 'By Far The Most Dangerous Drug Ever Made'
https://www.acsh.org/news/2017/09/11/tylenol-far-most-dangerous-drug-ever-made-11711

--- Add Link to Opioid Naive Dosing Calculator from Practical Pain Management :
The Practical Pain Management link below has an excellent calculator for determining initial dosage for the opioid naive. It gives tips on how to calculate, dosing intervals (which is a common error in prescribing), pharmacodynamics and pharmacokinetics, as well as tips and warnings about different formulations and adverse effects. They also provide a conversion calculator if a drug change is necessary. It is an excellent starting tool without bias.
https://opioidcalculator.practicalpainmanagement.com/starting.php

Pg. 10 - MME
No patients should be identified as higher risk based on MME. MME is junk science that does not reflect the pharmacodynamics and pharmacokinetics of opioid therapy. Current data shows that it's not necessarily the higher dosage that creates higher risk but rather changing dosages such as when patients are subjected to forced tapers or stopping 'cold turkey' and then resuming previous dosages. By putting 90 in here, the board is effectively stating that 90 MME is still a threshold of importance and it shouldn't be. There is no doubt in my mind that this will be interpreted as an endorsement of the 2016 CDC opioid guidelines if this is left in.. The rationale to prescribe **any** dosage should be documented in the patient's medical record, not just 90 MME. There is no reason to put that number in there absent intent to enforce the previous CDC 90 MME threshold. Nothing you say after that number matters.

Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730786?resultClick=3

The fact that CA law uses this metric is despicable and is something the board should seek to change. Most patients will never need Naloxone yet of great concern is that I am finding in the online communities that clinicians often force patients to accept the prescription or forgo opioid therapy. This should not be allowed. Patients accepting Naloxone prescriptions are often falsely assumed to be at high risk and inadvertently or purposely labeled as having an opioid use disorder in spite of never having any aberrant behavior or adverse events. It is particularly common for insurance companies to make this mistake. There is even an anecdotal report of a nurse who was denied life insurance because she purchased Naloxone to have on hand when she volunteers to help people on the streets with OUD, thus having Naloxone on your Rx record can be detrimental. Even patients who live alone and have no way to dispense the Naloxone are being forced to accept it. This should not be happening. Patients have the right by law to refuse Naloxone prescriptions and should be counseled as such.

Current Text:
"*Some clinicians have questioned the conceptual validity of MME because there is a lack of consensus regarding a universally accepted opioid-conversion method for patients taking opioids chronically. Despite these concerns, calculating the total daily dose of opioids can be useful in identifying patients who may benefit from closer monitoring,reduction or tapering of opioids, being offered a prescription for naloxone, or other measures to reduce risk of overdose. The CDC has developed a fact sheet titled Calculating Total Daily Dose of Opioids that provides one method for calculating a daily dose of opioids. The selection of an opioid dosage for a patient is a clinical decision made on a case-by-case basis in order to provide an individualized, patient-centered treatment plan. The risk to a patient increases as dosages increase and the rationale for the decision to prescribe a dosage ≥ 90 MMEs should be documented in the patient's medical record. California law requires that a prescription for naloxone be offered to a patient when the dosage ≥ 90 MMEs."*

---Change the above paragraph to:
Amended Text:
"*Some clinicians have questioned the conceptual validity of MME because there is a lack of consensus regarding a universally accepted opioid-conversion method for patients taking opioids chronically. Despite these concerns, calculating the total daily dose of opioids can be useful in identifying patients who are required by law to be offered a prescription for Naloxone. California law requires that a prescription for naloxone be* ***offered*** *to a patient when the dosage is ≥ 90 MME.. The risk to a patient increases as dosages change. Caution should be used when changing dosages and rationale for dosage changes should be documented in the patient's record. Clinicians should make it clear to the patient that they are not required to accept the Naloxone and that no one can force them to purchase it as a requirement of receiving opioid treatment."*

---**The CDC link should be deleted as it represents biased, misleading information that is widely known to be inaccurate and derived by inappropriate research standards and mass conflicts of interest. (They didn't even meet their own standards for research.) Also, there are safety concerns with the CDC opioid calculator. No links to CDC should be used anywhere in this document.**
Safety concerns with the CDC opioid calculator
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5739114/

--- Add the MME formula in the paragraph and add the conversion factor chart to the appendix. Or, put both in the appendix.
Example:
To calculate daily MME:
Dose size x Doses per Day x MME Factor = MME per Day
Example: Hydrocodone 5mg QID
5mg x 4 doses x 1 = 20 MME/day
*MME Conversion Factor Chart is located in the Appendix.****(can link the word "Appendix" to the exact page where it is located.)***

Example of Conversion Factors Chart:
Common Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors
OPIOID (UNITS) CONVERSION FACTOR
Codeine (mg) 0.15
Fentanyl patch (mcg) 7.2
Hydrocodone (mg) 1
Hydromorphone (mg) 4
9
Meperidine (mg) 0.1
Morphine (mg) 1
Oxycodone (mg) 1.5
Tramadol (mg) 0.1

Note:
The MME conversion factor for fentanyl patches is based on the assumption that one milligram of parenteral fentanyl is equivalent to 100 milligrams of oral morphine and that one patch delivers the dispensed micrograms per hour over a 24 hour day. Example: 25 ug/hr fentanyl patch X 24 hrs = 600 ug/day fentanyl = 60 mg/day oral morphine milligram equivalent. In other words, the conversion factor not accounting for days of use would be 60/25 or 2.4. However, since the fentanyl patch remains in place for 3 days, we have multiplied the conversion factor by 3 (2.4 X 3 = 7.2). In this example, MME/day for ten 25 µg/hr fentanyl patches dispensed for use over 30 days would work out as follows: Example: 25 ug/hr fentanyl patch X (10 patches/30 days) X 7.2 = 60 MME/day. Please note that because this allowance has been made based on the typical dosage of one fentanyl patch per 3 days, you should first change all Days Supply in your prescription data to follow this standard, i.e., Days Supply for fentanyl patches= # of patches X 3.

Conversion Factor Examples taken from the following links:
https://medicaid.utah.gov/Documents/files/Opioid-Morphine-EQ-Conversion-Factors.pdf
https://www.unmc.edu/NebraskaGWEP/wp-content/uploads/2020/01/052718_COM-IntMEd_Opioid-Pocket-Card_4x6.pdf

Pg. 11 COUNSELING PATIENTS ON OVERDOSE RISK AND RESPONSE
---Delete link "Prescribe to Prevent" as it contains information known to be false (ie. 60% of opioid overdose deaths are in medical users). Not even close to true. Information came from CDC.

Ongoing Patient Assessment
"• Conduct urine drug testing and review CURES reports as described elsewhere in this document."

--- Change to:
"Conduct urine drug testing as appropriate and review CURES reports as described elsewhere in this document."

Pg. 12 Compliance Monitoring

“Direct referral to a substance use disorder treatment program that provides medication-assisted therapy (MAT) may be offered depending on severity of misuse and if opioids are being stopped abruptly.”
---Note: Opioids should never be stopped abruptly in patients being treated for moderate to severe chronic pain. Chronic pain patients cannot withstand abrupt withdrawal due to the physiological impact of severe pain on the body. This can cause severe symptoms, including death. Clinicians should be advised against this. Strike the highlighted text and put a period after misuse.

Pg. 13 Urine Drug Testing
Note: Drug testing without medical necessity is a violation of the 4th amendment thus screening should not be mandatory.
“Patients prescribed certain pain medications should not be forced to consent to annual drug testing as a condition of treatment. This mandatory drug testing simply goes too far. The Fourth Amendment to the U.S. Constitution offers protection from government-mandated searches unless there is cause or justification.

The ACLU of Indiana challenged this rule in court, saying the testing constituted an unreasonable search, and therefore violated the Fourth Amendment. Our class-action lawsuit sought to prohibit the Medical Licensing Board from requiring the drug testing when that testing is not medically indicated and from requiring patients to sign a treatment agreement consenting to the testing.”

ACLU Challenges Required Drug Screening for Patients on Pain Medication
https://www.aclu-in.org/en/news/aclu-challenges-required-drug-testing-patients-pain-medications

For patients who are already on LTOT and doing well, UDTs are not necessary and, when added to the record, may stigmatize the patient and lead others who view the chart to falsely believe aberrant behavior has developed. This could be especially detrimental to patients whose charts are reviewed annually for disability purposes where such documentation could cause a knee-jerk reaction and lead to a loss of benefits and inability to get appropriate care.

It is crucial that the board protect doctors who recognize they are treating legacy patients who are vulnerable to stigma, discrimination, and loss of benefits, and who might very well be unintentionally harmed by adding unnecessary and misleading documentation to the patient’s medical record. Therefore, it is critical that such mitigation strategies not be required or strongly worded to imply there is no room for individual decision making.

Current Text:
“All patients on long-term opioid therapy should have periodic urine drug tests (UDT). Physicians should use urine drug testing before starting opioid therapy or when completely taking over for another prescriber and perform urine drug testing at least annually. The annual requirement for UDT can be performed using qualitative screening

test such as an immunoassay and does not require quantitative testing. Consider more frequent testing for higher risk individuals or at the time of aberrant behavior. These patients may require broader (more drug classes) and more specific quantitative testing based on clinical presentation.

Properly performed urine drug testing involves two steps: an initial screening test followed by confirmatory testing for substances with positive screening results. The use of confirmatory testing can add substantial costs and should be based on the need to detect specific opioids, such as those that are being prescribed, and those that cannot be identified on standard immunoassays or in the presence of unexpected toxicology test results. Restricting confirmatory testing to situations and substances for which results can reasonably be expected to affect patient management can reduce costs of toxicology testing."

--- Change to:
Amended Text:
"Patients on long-term opioid therapy can have periodic urine drug tests (UDT) ***as needed****. Physicians can use urine drug testing before starting opioid therapy or when completely taking over for another prescriber* ***as applicable****. UDTs can be performed using a qualitative screening test such as an immunoassay and does not require quantitative testing. Consider more frequent testing for higher risk individuals or at the time of aberrant behavior. These patients may require broader (more drug classes) and more specific quantitative testing based on clinical presentation. Properly performed urine drug testing involves two steps: an initial screening test followed by confirmatory testing for substances with positive screening results. The use of confirmatory testing can add substantial costs and should be based on the need to detect specific opioids, such as those that are being prescribed, and those that cannot be identified on standard immunoassays or in the presence of unexpected toxicology test results. Restricting confirmatory testing to situations and substances for which results can reasonably be expected to affect patient management can reduce costs of toxicology testing."*

---Pill Counting should be removed entirely. Stop treating patients like criminals.

Pg. 15 Taper Trial
---Add: "or reverse"
"For other patients, increased symptoms may indicate the need to stop or reverse a taper."
---Add: "addiction specialist" before the word attorney
"If a patient is known to be abusing a medication, initiating an opioid wean may be appropriate. Consultation with an addiction specialist, attorney, and/or one's malpractice insurance carrier may also be prudent in these cases."

Pg. 17 Medical Records
"An adequate medical record includes, but is not limited to, the documentation of the: patient consent and*, if needed,* the pain management agreement"
---Add "if needed"

Pg. 21 Emergency Medicine

---Remove the link “Safe Pain Medicine Prescribing”... due to non-patient centered directives and false and misleading information. This link, without a doubt, contributed to the harm pain patients have experienced over the last 6 years.

This link is the opposite of patient centered care and has little to do with the ER. It tells doctors “Don’t prescribe” for certain conditions rather than addressing patients on a case-by-case basis and it contains a multitude of information that we now know to be false and misleading. Furthermore, it links to outdated resources and opioid guidelines in other states that are not based on science or good medical practice. I’m deeply concerned that this was included in this document. It does not align with this document or the facts as we know them. It’s right out of the PROP misinformation campaign. We are going to have a lot of work to do to correct the propaganda and subsequent abuse in the setting of Emergency Medicine due to this link.

It should be noted that many chronic pain patients would rather die than go to the ER and be subjected to the interrogation, humiliation, and malpractice that they have experienced in the ER. They are assumed to be drug seeking from the minute they arrive, treated with contempt, and often not evaluated properly for new conditions. Others will go to the ER only if they are feeling like they are going to die without medical intervention. Rarely do they seek additional pain medication for their chronic condition. If a patient being treated with LTOT shows up in the ER, you can bet their condition is serious and likely not related to their chronic condition(s).

I understand that there are in fact “drug seekers” that show up in the ER but it appears more often than not that legitimate patients with chronic illness are impacted far more than non-medical users attempting to feign illness for pain meds. Some ERs even have signs saying they will not prescribe to chronic pain patients in the ER. I don’t know if this disgusting behavior in the ER is due to them believing the false narrative that CDC initiated, fear of MBC/DEA, or simply because they loathe pain patients but it needs to stop.
Patients must be properly evaluated in the ER whether they are pain patients or not. Their pain must be treated if a new condition is found and the patient’s treating physician should be notified of the new condition and also if there is an exacerbation of their chronic condition.

ER docs should work with the patient’s physician to ensure appropriate treatment of pain while in the ER and until appropriate follow-up with their treating physician can be achieved. This may include having a dialogue with the pharmacy to make sure additional pain medication can be obtained until the patient can see their treating physician. There should be a way for clinicians to put a designation in the medical record that shows that the patient is legit and deserves the care and medical intervention afforded every other person in the ER. Do we need ID badges that say “okay to treat like a human being”?

Even if a drug seeker does come into the ER, clinicians should work with them to get them on MAT rather than dismissing them and leaving them to suffer withdrawal or self medicate with lethal drugs on the street. Where is the compassion?

Pg. 21 **-** Use Caution when Tapering Opioid Therapy
---Add: "*Tapers should be consensual."*

Pg. 22 - Older Adults
"Pain in older adults is common and management is often more complex because of polypharmacy, changes in pharmacodynamics and cognitive and functional declines. As with all patients with mild to moderate pain, acetaminophen is typically considered a first-line treatment."
---Strike the words "moderate".
The second sentence goes against manufacturers' guidelines. Acetaminophen is not for moderate pain. It says on the bottle: "Uses: temporarily relieves minor aches and pains"...

---Change to reflect manufacturer's guidelines and insert safeguards regarding toxicity mentioned earlier:
"Pain in older adults is common and management is often more complex because of polypharmacy, changes in pharmacodynamics and cognitive and functional declines. As with all patients with mild pain, acetaminophen is typically considered a first-line treatment but is not advised when the max dose is required on a daily long term basis due to the potential for hepatic toxicity and accidental overdose. Patients should be cautioned that the toxic dose is very close to the max daily dosage so care should be taken when dosing. Tests evaluating hepatic toxicity should be done periodically in patients with ongoing use."

Acetaminophen Toxicity
https://www.ncbi.nlm.nih.gov/books/NBK441917/

---Add the link above to the paragraph above.
"NSAIDs can also be helpful but older adults can be more prone to side effects (gastrointestinal and renal toxicity, bleeding). Opioid medications have a role in the management of severe pain but have higher rates of side effects in older patients including constipation, increased risk of falls and higher rates of respiratory depression."
---Add "for mild to moderate pain"
---Add "moderate to" after the words "management of" (if they can't take NSAIDS for moderate pain due to side-effects, opioids are the only alternative.)
---Add "MI"after "bleeding"
---Add "Monitoring for toxicity is necessary for ongoing daily use of NSAIDs."

"NSAIDs can also be helpful for mild to moderate pain but older adults can be more prone to side effects (gastrointestinal and renal toxicity, bleeding, MI). Monitoring for toxicity is necessary for ongoing daily use of NSAIDs. Opioid medications have a role in the management of moderate to severe pain but have higher rates of side effects in

older patients including constipation, increased risk of falls and higher rates of respiratory depression."

Because of higher rates of respiratory depression, consider offering a prescription for naloxone if the patient presents an increased risk of overdose or the dosage is ≥90MMEs/day. Clinicians should make it clear to the patient that they are not required to accept the Naloxone and that no one can force them to purchase it as a requirement of receiving opioid treatment."

---Add Clinicians should make it clear to the patient that they are not required to accept the Naloxone and that no one can force them to purchase it as a requirement of receiving opioid treatment."

Pg. 23 Pregnant Women
"Universal screening for substance use is recommended to be part of comprehensive obstetric care and done at the first prenatal visit. Routine screening should rely on validated screening tools, such as questionnaires including 4Ps, NIDA Quick Screen, and CRAFFT (for women 26 years or younger)."
---Pretty sure this is considered a violation of the 4th amendment. Do NOT do this.

ACLU Challenges Required Drug Testing for Patient on Pain Medication
https://www.aclu-in.org/en/news/aclu-challenges-required-drug-testing-patients-pain-medications

Pg. 24 Workers Comp
---ACOEM GLs are much more rigid. They should align their GLs with MBC.
" recommended morphine equivalent dose limit of no more than 50 mg/day. Higher doses should be prescribed only with documented commensurately greater functional benefit(s), comprehensive monitoring for adverse effects, informed consent, and careful consideration of risk versus benefit of such treatment. Chronic opioid use should be accompanied by informed consent, a treatment agreement, tracking of functional benefits, drug screening, and attempts at tapering."

--- The wording in the statement above is not acceptable. Does the board have the ability to force them to change their policy to align with this document? "Commensurately greater functional benefits"? Seriously? Who decides?

Pg. 25 Patients Prescribed Benzodiazepines
"Naloxone is an opioid antagonist and can be safely administered by laypersons with virtually no side effects and no effect **in the absence of opioids.**"
---Delete the above sentence. What is the purpose of the above sentence? Why would you give Naloxone as a rescue drug to someone who is not on opioids? There is no reason for this to be here. It doesn't work for benzodiazepines and if the person is on LTOT for severe pain, you risk deadly side-effects by giving it so you better be darn sure you know the person is already dying before giving it. Giving Naloxone to someone on LTOT for severe pain is never going to be "safely administered", even people with

moderate pain are going to be harshly impacted by immediate reversal, withdrawal, and likely severe pain. Administering Naloxone to people without moderate to severe pain is one thing, administering it to someone in pain is an entirely different story. I really think we need to rethink Naloxone use in chronic pain patients.

"CDC recommends that a prescription for naloxone be provided when opioid use ≥50 MMEs/day."
---Delete above sentence. MME is junk science. CDC has no evidence to support this recommendation and have already been found to use unsupported and cherry-picked research to advance their agenda. MBC should not support CDC until they can follow their own research rules.

"*California Law requires that the physician offer a prescription for naloxone to the patient when one or more of the following conditions are present: 1) the dosage of the opioid medication is ≥90 MMEs/day; 2) an opioid is prescribed concurrently with benzodiazepine (within a year from the date the benzodiazepine was dispensed); or 3) the patient presents with an increased risk for opioid overdose."*
---Add after "overdose." "*Clinicians should make it clear to the patient that they are not required to accept the Naloxone and that no one can force them to purchase it as a requirement of receiving opioid treatment."*