Agenda Item 3

From: [redacted]
Sent: Wednesday, June 22, 2022 9:51 PM
To: Robinson, Letitia@MBC <

Subject: Comment re: Prescribing Guidelines Meeting, July 14, 2022

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My comment re:
Interested Parties Meeting: Prescribing Guidelines on July 14, 2022

I support pain patients getting the medications they need without being treated with judgment or bias or having to beg for their medication. That being said, agenda item #4 mentions that **appropriate, safe, and effective pain treatment needs to be available**, yet therapeutic massage therapy is not even mentioned as part of a proposed protocol.

As a licensed massage therapist for twenty-seven years, I testify that nearly 100% of clients benefited from deep tissue massage therapy whether they were in acute, subacute, chronic, end-of-life care, high impact chronic pain, and intractable pain; they were able to manage and heal from pain, avoid surgeries that were not appropriate for them, and avoid, cut down, or get off of pain medications.

Pain medication masks the symptoms of pain that massage and movement therapy often heal. I suggest doctors incorporate skilled massage therapy, (which is effective in many cases more than physical therapy), into their pain protocols for pain patients who are interested for the best outcomes.

Also, many people, such as myself, are in intractable pain as a result of aggressive, unneeded, and non-consented surgery. I (continue to) request that plastic surgery laws in California be changed.

Prevention should be top priority.

Thank you,

Susan Lauren
(Redacted)

Comments on Draft California Prescribing Guidelines

Richard A Lawhern PhD and Stephen E Nadeau MD

June 2022

These joint comments are offered in response to a circulated invitation to attend an Interested Parties Meeting on July 14, 2022.

Richard Lawhern 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.

Stephen E Nadeau MD 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 BA Medical Center. Opinions expressed in this paper may not reflect positions of the US Veterans Administration.

A General Observation:

The term "risks" appears no less than 30 times in this 26-page document, and is frequently referenced to the 2016 CDC opioid guidelines. Unfortunately, many uses of the term in this document are largely not germane to actual medical practice.

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.

Moreover, nowhere do we see an admission in this document that is deeply buried a pending 2022 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. Therefore, opioid therapy should not be initiated without consideration by the clinician and patient of an "exit strategy" that could be used if opioid therapy is unsuccessful."

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 any reliable instrument for doing so in a defensible manner. This conflict between reality versus theory must inevitably exercise a powerful suppressing effect on the willingness of clinicians to risk sanctions or law enforcement persecution in order to treat their patients.

From this background, we must suggest that the emphasis on risk in the California Prescribing Guidelines is grossly over-hyped, reflecting many fundamental and fatal flaws in the CDC document to which it is closely related.

We offer three deeply researched references in evidence of this misdirection as it occurs in the California guidelines.

Atch 1: "Richard A Lawhern, "Comments on "CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022" [Submission to the US Federal Register, March 2022]

Ref 2: 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

Ref 3: 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

We urge that unless the California guidelines are to be outright repudiated and withdrawn, this draft should be withdrawn for an independent "red team review" and significant rewriting before publication. We also urge the insertion of explicit literature references for each of the claims of fact made in the guidelines.

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

Preamble:

The California guideline characterizes the goal of the 2016 CDC Guidelines as "to ensure that clinicians considered safer and more effective pain treatment in order to improve patient outcomes (i.e. reduced pain and improved function) as well as to reduce the number of patients who developed opioid use disorder, overdose, or experienced other opioid-related adverse events."

With the advantage of hindsight, clinicians now know that the CDC guidelines had no such effect – and could never have had such an effect, given that the so-called "opioid crisis" was not an outcome of over-prescribing by clinicians to legitimate pain patients in the first place. Data published by the US CDC itself reveals startlingly contradictory trends.

It is known, for instance, that seniors age 65 and over are prescribed opioids about 60% more often than young adults age 25-34. This is a natural outcome of the accumulation of chronic pain conditions over patient lifetimes. However, we also know that opioid-overdose-related mortality is currently 400% higher in young adults than in seniors, and is dominated by self-administered poly-drug exposure including alcohol and illicit street drugs.

See Figure I and Figure 2 below, both extracted from CDC/SAMSA source data:

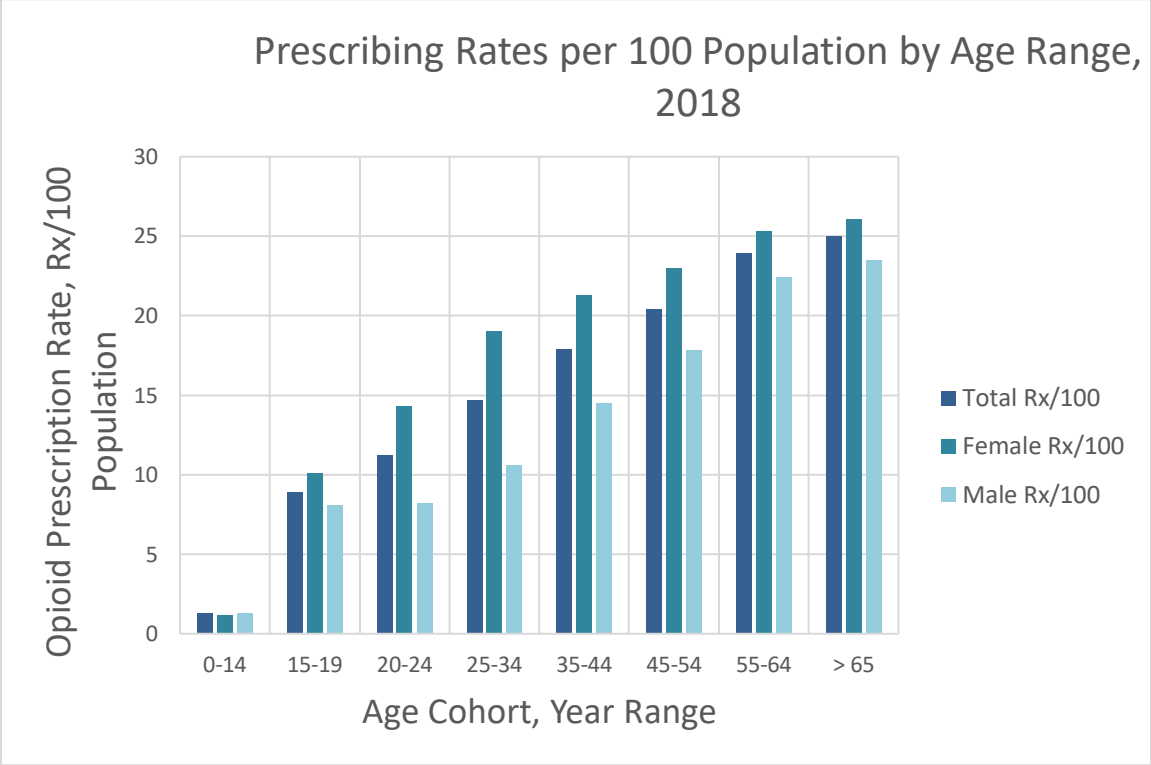

Figure 1: Prescribing Rates by Age Cohort

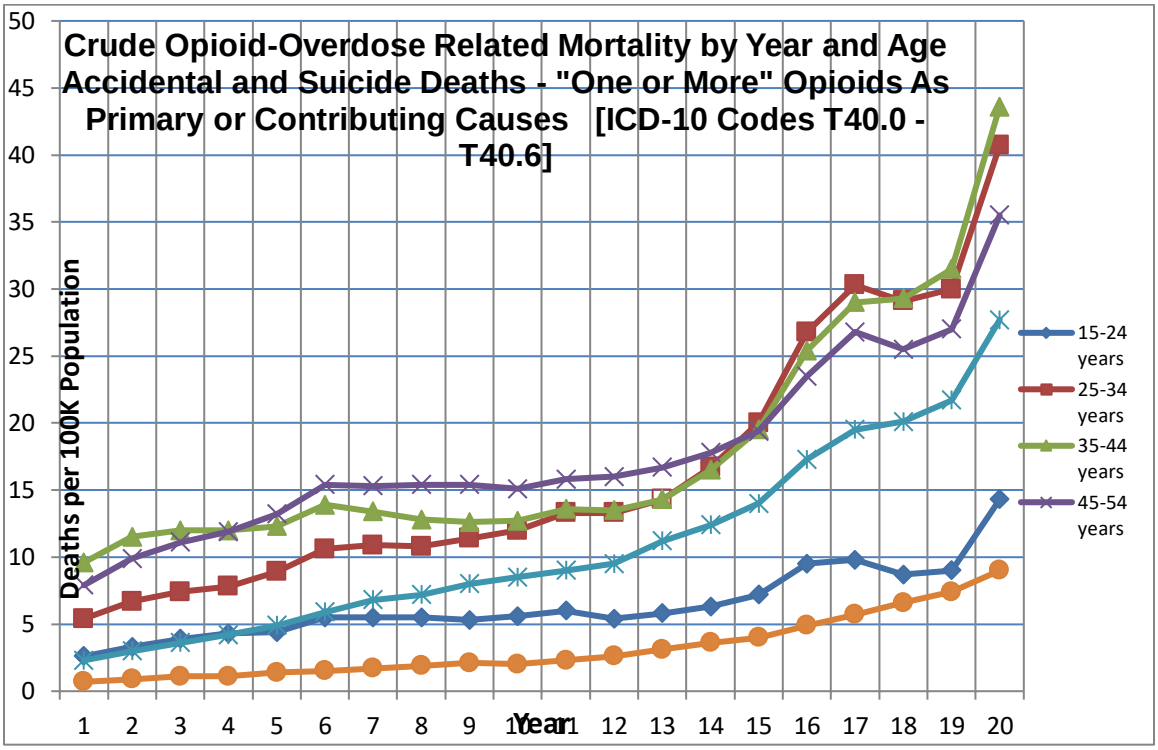

Figure 2: Overdose Related Mortality by Age and Year, 2001- 2020

In view of the data in these figures, it is simply 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.

Recommended Practices:

This section 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."

Authors' Observations: the practice of pain management in chronic patients is 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 3A]

Conditions of practice in addiction treatment are equally challenging. It is a fundamental error to presume that patients can simply be put on Buprenorphrin 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 3A: 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."

Authors' 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 have limited applicability 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 at least partially controlled by other means. Pain psychology has never undergone trials as a substitute for opioids.

As mentioned previously, there are no reliable patient profiling instruments for assessing 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. They 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 in 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 sit Ref 3]. Tellingly, the draft California Guideline document fails even to mention the terms “genetic” or “genomic”. This omission must be constructively addressed in detail.

Morphine Milligram Equivalent Dose

Authors’ Observations: The Opioid Workgroup of the Board of Scientific Advisors to the US National Centers for Injury Prevention and Control has 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 authors’ view, 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 must 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, and the California Guideline should explicitly advocate to this effect.

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.

Authors' Observations: As noted previously, the 90 MME per day 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 such 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

Authors' 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 this draft 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

Authors' 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 must 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/

CURES Reports also **Urine Drug Testing**

Authors' Observations: Law enforcement access to the CURES database must 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?

Pill Counting

Authors' Observations: The practice of pill counting is enormously destructive to the clinician-patient relationship, communicating an undeserved distrust in the patient's veracity and good will. If the patient is already being seen monthly in person or by video conference, then pill diversion will readily become apparent from the patient's repeated narratives of accidental loss or theft.

Discontinuing Opioid Therapy

This section includes the following wording:

> "Patients with unanticipated challenges to tapering, such as inability to make progress in tapering despite opioid-related harm, might have undiagnosed opioid use disorder."

Authors' Observations: It is 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]

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."

Authors' 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 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.

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, 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. [Figure 1 and 2 above]. 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.

Authors' 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 proposed "California Guidelines for Prescribing Controlled Substances for Pain " remains closely aligned to the 2016 and draft/proposed 2022 CDC Practice Guidelines for prescription of opioids to adults with chronic non-cancer pain. In the authors' view, this 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 potentially from financial and professional conflicts of interest among the CDC writers [Ref 12].

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

As long as the proposed California Guidelines remain aligned with CDC, they will almost certainly 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 possible. 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 can be written. One such framework is outlined in great detail in [Ref 3] of these comments. 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 13]. 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.

Attachment 1, Appendix 1 to these comments offers 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 CDC and California Medical Board reconsideration and refinement of the logic, goals and definitive medical evidence pertaining to treatment of pain.

Ref 12: Chad Kollas, Terri Lewis, Beverly Schechtman and Carrie Judy, "Roger Chou's Conflicts of Interest – the CDC's 2016 Guideline for Prescribing Opoids for Chronic Pain Lost its Clinical and Professional Integrity" *Palimed – A Hospice and Palliative Medicine Blog,* September 17, 2021. https://www.pallimed.org/2021/09/roger-chous-undisclosed-conflicts/

Ref 13 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/

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 source and severity of pain.

Titrate up opioids (when employed) to desired effect, monitoring for and managing for 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.

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From: Tim Munzing
Sent: Sunday, June 26, 2022 6:58 PM
To: Robinson, Letitia@MBC <Letitia.Robinson@mbc.ca.gov>

Subject: Comment - New MBC Opioid Guidelines

Just a brief comment - the opioid dosing is referred to as MED and MME. Morphine Milligram Equivalent is now preferred over Morphine Equivalent Dosing. I suggest the MED reference - page 9 - be changed to MME.As written it is confusing.

Thank you!
Tim

Tim Munzing, MD
(Redacted)

June 30, 2022

To the Medical Board of California,

My name is Rhonda Favero. I am 61 years old and live in California. I have suffered from severe chronic intractable pain for over thirty years. The primary causes of my pain are diagnosed as early severe degenerative cervical spine disease, Chiari malformation, Hydrocephalus, and Adhesive Arachnoiditis and subsequent nerve damage, and spinal cord impingement by bone spurs. I have worked with three pain management doctors through all available alternative step therapies without success. As a last resort, managed pain medication is the only treatment that has afforded me a reasonable quality of life; allowing me, until two years ago, to successfully work and volunteer part time, even being recognized by the state of California for my excellent volunteering efforts.

In 2017, my pain management doctor began reducing my dosages of pain medication and intentionally under-treating my intractable pain. He admitted that this was medically contraindicated, since my condition is worsening. But pressures from the DEA to comply with CDC dosing "guidelines" made him taper all his patients regardless of condition or impact on their quality of life. He fears DEA actions that would lead to prosecution if he treats under prevailing, medically indicated best practices. In addition, he has shared that scrutiny from the Medical Board of California under their Death Certificate Project has further restricted his ability to provide safe, adequate medical treatment to relieve suffering. His attorney had advised him that deviating from forced tapering of patients could lead to closure of his practice, leaving hundreds of patients with no treatment. He has shared that several of his colleagues have expressed to him similar concerns and many have closed their pain management practices to the detriment of their patients.

For me, this unwarranted reduction in pain medication dosing forced me into an unbearable quality of life (unrelenting pain, lack of sleep, limited activity, poor appetite, depression). Due to my worsening condition, I have been accepted in a palliative care program with the Visiting Nurses Association. Unfortunately, it took almost a year to find a pain management physician who would adequately treat my pain under the palliative care exemption frequently stated in the 2016 CDC guidelines. All of the doctors I consulted with declared concerns with DEA and Medical Board sanctions as reasons for not providing treatment. Without adequate pain treatment, I am not able to make the monthly 210 mile round trip to my pain management physician. The extended period of under-treatment caused me to leave my part-time job and stop volunteering.

Earlier this year, my pain management/palliative care physician moved their established practice from California to Oklahoma. One of the reasons for this was the recent passage of legislation in Oklahoma that protects medically necessary treatment of intractable pain patients and supports the rights of their physicians to provide treatment. Unfortunately, to continue being treated by this physician, I would have to move to Oklahoma. Once again, I was forced to search for a pain management physician in southern California. After several pain filled months, I found a compassionate physician to provide me with treatment.

Additionally, my pain management treatment has been negatively impacted by pharmacy and insurance company issues. The pharmacy I had used for over fifteen years has declined to fill my legitimate controlled medication prescriptions, stating that they fear scrutiny from the DEA and the Board of Pharmacy. Subsequently, the pharmacy that I have been using for the past several years has not been able to obtain my prescribed commercially available pain medication due to DEA regulated supply restrictions and quotas. This has caused my doctor to prescribe specially compounded pain medications. Since insurance companies do not cover compounded medications, my prescriptions costs have increased 2,200%.

Even the administrators for our insurance carrier are interpreting the CDC prescribing guidelines as strict regulations, causing physicians to spend an inordinate amount of time securing medication pre-authorizations and justifying medical diagnosis to people with no medical training. The CDC dosing guidelines state several

times they do not necessarily apply to patients being treated for long-term, chronic pain and cancer/palliative/hospice patients yet innocent doctors are being bullied and threatened. The broad brush of government regulations and misapplied guidelines is causing unnecessary suffering for myself and countless, law-abiding intractable pain sufferers. Even cancer patients who only have a short time to live are dying in agony. Intractable pain is very individualized and should be controlled by responsible pain management physicians, not government agencies and insurance companies.

My husband and I appreciate the efforts of the Board to revise your *Guidelines for Prescribing Controlled Substances for Pain* to improve patient outcomes and protect physicians. Please consider these suggested changes:

- Eliminate all references to Morphine Equivalent Dose limitations. Stating dose limitations, even as guidelines, is more often than not assumed to be maximum regulatory limitations and are broadly applied to all patient populations. This is the crux of the overwhelming harms to patients caused by the 2016 CDC Prescribing Guidelines. The Board has an opportunity to mitigate further harm to pain patients in California by not referencing the flawed CDC Guidelines. Referencing AMA recommendations would be more appropriate.
- In the section pertaining to Discontinuing Opioid Therapy, we believe that the 30-day notice recommendation is insufficient. The expanding shortage of qualified pain management physicians make it very difficult for patients to find appropriate care. Our personal experience has involved up to eight months finding a new physician.
- Please include additional guidance relative to patients in palliative care. This should include guidance to physicians on qualifying intractable pain patients for palliative care.

Thank you,

Rhonda and Lawrence Favero
(Redacted)

Thank you for this opportunity to provide written comment about this important update. The upcoming July 14th is meeting is an encouraging follow on to last year's April 21, 2021 "Stakeholder" workshop. During that workshop, I was pleasantly surprised by the responses of Dr. Thorpe, and then board member, Dr. Krauss, to Kristen Ogden's excellent public comment. Their responses gave me hope, somebody in authority understands.

My name is Francis Goddard. I have a Master of Science in Civil Engineering. I am, and have been, a licensed Professional Engineer in California since 1979. I am an advocate for my wife, who in 1997 was diagnosed with bi-lateral Avascular Necrosis, or AVN, in all her long bones, both arms and legs. A few months later she was also diagnosed with breast cancer. Following a mastectomy, chemotherapy, and reconstruction surgery, we are thankful she has remained breast cancer free, although the chemotherapy increased her AVN.

My wife also suffers degenerative disc disease in her neck and lower spine. She has undergone four fusions in her neck. The first three anterior. and the last posterior which fused five discs into a single unit. Yet, one wrong move of her head instantaneously brings on a severe migraine. But the life changer for both her and I is her AVN and the pain it creates. AVN pain is claimed to be second only to that of bone cancer.

Only after six years of orthopedic consultations, three hip replacement surgeries, and a litany of pain control protocols failed to provide adequate relief, her pain management physician resorted to a combined opioid pain management protocol beginning in 2003. This protocol remained static both in strength and quantity for several years at much higher quantities and strengths than she is now prescribed. These medications, as prescribed by this physician, and safely used by my wife did not eliminate her pain, but for several years provided enough pain relief to give her a reasonable quality of life.

That changed with the inception of our government's war on the "opioid epidemic" and the CDC's 2016 "Opioid Prescribing Guidelines" with their imbedded MME "recommendations". Despite all subsequent "clarifying guidance" these MME recommendations have become de facto upper prescribing limits. Physicians who exceed these "recommendations", especially if they have numerous complex pain patients warranting higher MME prescribing, are at professional risk. As a result of this very real risk and under ever mounting pressure, her pain management physician was "forced" to steadily lower, both in quantity and strength the medication which had been providing significant pain control. Now, mostly bed or couchbound, my wife's quality of life has dramatically declined. I too have suffered. I do not experience her physical pain, but I certainly suffer our mutual stress, mental anguish, and loss of life's pleasures.

I object to California adding legitimacy to the CDC's guidelines which have so harmed innocent vulnerable chronic pain patients. Even though the CDC guidelines are currently being revised, I doubt they will be less harmful to chronic pain patients. When I saw initial media reports about MME's being removed from the draft revised guidelines, I was ecstatic. That feeling of relief evaporated as I read the gargantuan 211-page document. Although referrals to 50 and 90 MMEs have been removed from the 12 top tier level guidelines, references to 50 MME are imbedded throughout the subordinate

“Implementation Considerations” and “Supporting Rationale” sections of the related numbered “guideline”. It is clear the drafters of the draft revised CDC guidelines intend to further push their anti-opioid agenda but are now employing a tactic of subterfuge. A tactic called out by our 28th US President, Woodrow Wilson with these words: “No one who has read official documents needs to be told how easy it is to conceal the essential truth under the apparently candid and all-disclosing phrases of a voluminous and particularizing report…”

Just as the 2016 CDC Guidelines caused grave harm to severe chronic pain patients and their physicians, the CDC’s draft revision will continue to do so. But now, “50 MME”, not “90 MME”, will become the new de facto upper prescribing limit. The inclusion in California’s revised opioid guidelines of segments of the September 7, 2021, CA Dept of Public Health alert to physicians, while welcome, is not sufficient to convince most CA physicians it is professionally or personally “safe” for them to exceed the bogus CDC “recommendations”. Please explicitly state in, California’s revised opioid guidelines, CA physicians are not subject to the CDC’s revised Guidelines MME thresholds.

Francis Goddard

From: Rebecca McCaslin
Sent: Friday, July 1, 2022 4:25 PM
To: Robinson, Letitia@MBC <Letitia.Robinson@mbc.ca.gov>
Subject: CA OPIOID PRESCRIBING RECCOMMENDATIONS

Dear Leticia,

Thank you for allowing patient input into prescribing guidelines for CA Physicians. Draconian times are here in the U.S. as we are all witnessing and experiencing misguided rules and punishments applied to patients, women and seniors, not based on Science, but religion, politics and ignorance. Social media gives every lunatic a voice and I do feel for parents who have lost a child due to a fentanyl overdose, but they are NOT the majority of patients who desperately need pain relief, yet their misguided aim at prescribers unleashed a hellstorm.

Most opioid prescriptions are for seniors, over age 55+ with chronic, progressive conditions.Those conditions eventually lead to death, because there isn't a cure. I have had an autoimmune disease since childhood, which has morphed into more sinister versions as I aged. I treated it with EVERY exercise, OTC., vitamin, diet, lifestyle, geographic relocation from east to west,biofeedback, P.T., surgeries, decongestants, hormones, steroids,oxygen, psychologists, SSRI's,biofeedback, minerals, etc., but it still knocked me down. Finally saw a doctor who prescribed pain medication, which I had refused until menopause made it unbearable, and it has been the medicine that allows me to live a full days, WHEN I can get adequate care. Doctors are terrified to prescribe above a random MME amount that is not scientifically founded. I'm below that range and lose days due to being bedridden.I've had all the pre-med classes at UCSD long ago and understand how this works. My education was hindered by my condition, so I was a very well educated science teacher for 37+years. I also know how damaging acetaminophen and ibuprofen are on the kidneys and liver, so that option shouldn't be pushed as a stand in for opioids. At this point in my life, opioids are the best and least damaging medication I can take for a full life. I'm getting worse and currently developed Polymyalgia Rhem., which has set me back. Being cut way back on the opiods in March was a contributing factor, due to activity curtailment and rise in inflammation. Allowing non-scientific rules to ruin peoples late years is so wrong, almost amoral, because it's unjustified.

We are not teens getting high, we're old, sick and weary from being "managed".

Old age is a degenerative illness. Prescribers should not have limits or be threatened with license removal for treating old age, chronically ill patients, who have had NO issue with their medications in the past until this recent, nonsense "war on drugs" used to show the public that the overfunded policing of the DEA is making progress in fentanyl overdoses by targeting doctors? Insanity in action!

SIMPLY: No limits, no MME's for old age(60+y.o.) chronically ill patients.(Even medicare got involved by agreeing with this MME nonsense, tsk) No threats to doctors trying to make the last years of patients' lives bearable, without the threat of losing their license. Stop the madness.

Best regards;

Rebecca McCaslin

From: Virginia Farr
Sent: Friday, July 1, 2022 1:00 AM
To: Robinson, Letitia@MBC; Kristina Daniel Lawson
Subject: Pain Guidelines Draft

Thank you for updating the pain guidelines.

Here are my concerns:

Medical Professional Burn Out

- Inability to hear concerns
- Overwhelmed with tasks, charting, and electronic medical records

Lack of time to research and self-educate on vital medical research.

Trauma/adverse childhood events

- Traumatic stress and adverse childhood experiences are often the root cause of pain, while PTSD related to pain is mentioned once, it does not address the fact the majority of physicians do not have sufficient training in traumatic stress to properly assess or address traumatic stress.
- Trauma-informed care is not taught in medical school. Most physicians do not provide the necessary care for those with trauma.
- Assessing for adverse childhood experiences is not listed as part of the guidelines, yet is often the root cause for pain.
- Trauma therapy is not listed as a part of integrative care.
- Trauma education is not listed
- Trauma informed education is not listed.
- Trauma impacts communication on many levels. Without trauma informed care the patient too often goes unheard or misunderstood.

Dx Overshadowing

- Dx Overshadowing is often experienced in the medical system. It is a **Joint Commission Sentinel Event Alert 65**. Often patients with pain are Dx Overshadowed. This needs to be addressed and medical professionals need to be educated on preventing this. It often leads to events like missed cancer diagnosis.
- Patients are too often prescribed psych meds instead of addressing the pain.
- Biases

Prevention:

- Too often pain is caused by medical events such as liposuction, surgery, and other medical events.
- Protocols and CME must be put into place to prevent preventable events leading to pain.

Polypharma:

- Patients are often over subscribed medications combinations (beyond pain medications), often ignoring the root cause of the pain. Many of these medications have severe adverse side effects including neuropsych impacts. These side effects are often ignored or misinterpreted as a result of the illness vs the result of the polypharm.
- Too many patients are prescribed psych medications, when the root is pain and often trauma. These medications can be very harmful.
- Nonpsychotropic Medication-Induced neuropsychiatric effects

• Adverse drug events (ADEs) affect millions of people each year.
• 3.5 million physician office visits, approximately 1 million emergency department visits, and almost 125,000 hospital admissions annually
• Neuropsychiatric effects constitute up to 30% of ADEs and are associated with considerable morbidity and mortality
• 7% to 25% of individuals presenting with a first episode of psychosis, the condition may be substance- or medication-induced.
• 540 million 30-day-supply prescriptions of medications labeled for suicide risk were filled in the United States
-

Progression of illness/injury

- Patients often have a negative test, but the illness/injury progressively gets worse, since the original testing was done and negative, it is often very challenging to obtain a repeat test.

Reproductive

- Reproductive pain is often missed or patients told it is their heads.
- Refer to book Ask Me about My Uterus
- Most doctors do not have the knowledge how to assess the pelvic floor for pain or to refer to a pelvic pain physical therapist.
- Refer to book: Pelvic Pain Explained
- There is a lack of knowledge about other root causes of pain such as pudendal nerve pain. obturator internus pain and inflammatory vaginitis - all which can cause severe pelvic pain.

Fascia

- Often the root cause of pain, but is too often missed

Pharmacogenomic test

- Often covered by insurance
- Can detect the genetic metabolism ability of many drugs to prevent over/under medicating.
- Antidepressants
  - Anxiolytics and Hypnotics
  - Antipsychotics
  - Mood Stabilizers
  - Stimulants
  - Non-stimulants
- I believe some pharmacogenomic can also detect addiction risks

Pharma education

- Trend to not knowing the cause of symptoms are medical side effects vs illness symptoms.

Integrative care

- Massage
- Diet
- Trauma therapy
- Somatic therapy
- Fascia work

Infections

- Missed infections and other components such as lyme or mold.

Medical errors

- How patients are treated after an error-extremely challenging to obtain care.
- Improper and often harmful documentation.

Diet

- Can be the root cause, but is often also missed.

Too many doctors prescribing

On Fri, Jul 1, 2022 at 10:57 AM Virginia Farr wrote:

Thank you,

I would like to add this video from a pain and traumatic stress expert- Davis Bennet.

Also, Ace Aware website that should be the foundation of care.

Lastly, the role of insurance companies in pain management and trauma management results in challenging care environments.

Thank you

From: Virginia Farr
Sent: Friday, July 1, 2022 1:20 PM
To: Robinson, Letitia@MBC
Subject: Re: Pain Guidelines Draft

Also, the book Communication Trauma.

Trauma greatly impacts the communication centers. With medical professionals uninformed often critical pieces of information is missed.
Patients end up experiencing more harm. Often leading to avoidance of medical systems.

They often also experience Poly Pharma while missing the root cause, which is often trauma.

https://naamayehuda.com/communicating-trauma/

Along with the role of the microbiome and psychobiotics in pain prevention and treating pain. Including the gut brain axis.

Thank you

From: Virginia Farr
Sent: Sunday, July 3, 2022 1:28 PM
To: Kristina Daniel Lawson; Robinson, Letitia@MBC
Subject: Fwd: Well brain pain assessment app

Hello,

I will like to add one more recommendation which is a technology-based app that does monthly pain and mood assessments.

It is also billable to the health insurance companies.
It helps to manage pain and prevent ER visits. It also assess for suicide risk.

Well Brain is one app, it also provides meditation tracks.

Here are some of the questions it asks: (Provided screen prints from Provider.Wellbrain.com)

From: Ms. Heather Grace
Sent: Sunday, July 3, 2022 8:45 PM
To: Robinson, Letitia@MBC
Subject: Comments on Draft Guidelines for Prescribing Controlled Substances for Pain

Ms. Robinson,

Please share my input below with all of the Board members. I thank you so much for your time, and look forward to the meeting July 14th! The document is also attached for the sake of convenience.

The Impending Demise of Pain Management — It's Not Too Late, YET

An Open Letter To "The Powers That Be" by Heather Grace • July 3, 2022
EFFECTIVE PAIN MANAGEMENT HEALS, I'M LIVING PROOF: MY STORY
My journey into what would become debilitating pain began at age 19 when my neck was injured in a head-on collision caused by a drunk driver. Being a backseat passenger in an older car meant there were no headrests. I healed as best I could after the accident with chiropractic care and exercise.

I was young, so even though I told myself "I'm ok/I'll be fine," I knew I wasn't quite the same as before. Nearly a decade of work in the IT field worsened the severity of my injury. It was due to faulty ergonomics. Between the reasons for my condition, the horrors of the worker's compensation system and the onset of severe pain, it began to feel like I was in free fall.

Somehow that kept going, until I ended up in the 7th layer of hell: A neurological problem so severe that on my first visit with the preeminent pain management specialist in the country, he said: "Normal is out the window for you."

It was the worst thing I'd ever heard, so I began sobbing. What he said wasn't cruel however, it was honest. He could see that my body was pretty broken after 7 long years of workers' comp care that included TWO botched neurosurgeries and ONE spinal discectomy + fusion surgery which came far too late to be a good thing whatsoever.

Although I didn't know it back then, I'd lived with the genetic illness Ehlers Danlos Syndrome my whole life. After everything that happened, I was also left with severe nerve damage and neurological pain. I was diagnosed with Intractable Pain and Complex Regional Pain Syndrome Type II. CRPS II is in fact not regional at all, but has spread to the whole body thanks to the impact on the spinal column and brain. In case you've never heard of Intractable Pain/Intractable Pain Syndrome , I'll explain…

DIFFERENCES BETWEEN CHRONIC PAIN & INTRACTABLE PAIN SYNDROME
Intractable Pain Syndrome isn't understood in mainstream medicine because it's not very common. This makes it even less likely that the average person has heard of it. In fact, until I was diagnosed, even working in Continuing Medical Education for 10 years I'd never heard of it! So unfortunately, I didn't know that it was possible to be in severe unceasing pain, much less understand the complete picture. People with Intractable Pain experience major health problems over many decades of their lives because of the toll this magnitude of pain takes on the body.

IPS must be known, recognized and treated in like any other long-term medical problem such as rheumatoid arthritis, diabetes or asthma. Physical, psychological and pharmaceutical measures must be taken. Treatment for this complex and disabling diagnosis must be taken seriously and done correctly. Most people don't understand that there are vital reasons for the use of pain medication beyond its use in cancer treatment and hospice settings.

Use of pain meds must be acceptable to all concerned parties in the patient's life for the treatment to be successful, including their physician and their close family members. That's true even if the doctor &/or

loved ones themselves don't fully grasp the need for the use high dose pain meds that are (unfortunately) abusable.

CHARACTERISTICS OF INTRACTABLE PAIN SYNDROME

- Pain is Constant, 24/7
- Treatment is Daily, Around the Clock
- Elevated Blood Pressure and Pulse
- Elevated Temperature & Breathing
- Anorexia/Malnutrition
- Insomnia
- Depression, Hopelessness
- Endocrine (Hormone) Abnormalities
- Elevated Inflammatory Markers OFTEN
- Restriction of Life Activities, Such As Mobility
- Decreased Capability for Requirements of Daily Living

Intractable Pain requires a different approach than Chronic Pain because it is a totally different condition. IP patients need specialized care that's beyond the level of most physicians who treat pain. A doctor who's knowledgeable about this condition and how to treat it is crucial.

The above information provided by IntractablePainSyndrome.com
After all of the above was explained to me by my phenomenal doctor, I realized I was indeed living in the past. To move forward with my life, I had to stop pinning all my hopes on the idea of "normal."

Because of what I'd been through and the fact that I was so focused on getting back to that life, I couldn't move on. I had to grieve the loss of my former life, my normalcy. Once I did, a door was opened to a meaningful future for me.

MY LIFE TODAY: FROM PAIN PATIENT TO ADVOCATE & BEYOND
Thanks to amazing treatment with a physician who also helped me focus on a future full of possibilities, I'm living again in a way I'd didn't think was possible when I first sat down with my doctor in January 2006.

My doctor found the right treatment for me as an individual. As a result, I've reduced my medication dose slowly over the years. This was at my request, because it was time — it was not because the change to dosing set forth by the CDC was forced upon me. I'm now taking less than 1/6th the pain medication I did at the outset. That's because I've experienced neurogenesis, aka healing. Just reduced my dose again this week!

That's right, its possible for people like me to heal, albeit very slowly over time when they get the care they need. Despite the severity of my condition(s) and my even requiring pain medication in the first place, I'm doing well.

Contrary to popular opinion, patients who get the proper dose of pain meds don't require more and more medication. The opposite is actually true! While some patients' dosages stay the same, many of us are able to lower our doses when our health improves. For me, that's happened 8 times to date. I believe I will continue on this trajectory.

I've come so far already. In 2004 when I left the job I loved awaiting 2 major surgeries, I believed I'd never work again. I was finally able to obtain a full time job (with benefits!) and sustain FT employment for over a year beginning in March 2020. That's a major accomplishment!
In the past I'd tried and failed to keep a full-time job many times, but it's finally worked out for me. It required major effort to get to this point, but I got here because I had a foundation of long-term effective pain management which lessened the impact of pain on my overall wellness.

In case you're wondering, pain medication has always been but one part of my treatment. It does not define my care, nor my life. Pain meds are merely a tool I've used to get well and it's a tool that's worked for me. Each patient should have access to individualized pain care with the treatment options that best work for them. It's crucial for patients if they're ever going to see their health improve.
I couldn't imagine how far I would come all those years ago, and yet, it happened thanks to a pain care regimen designed to meet my specific needs. I'm thankful for the tools I was so fortunate to have, because they helped me get my life back on track.

I'm much more thankful to my doctor, and to the wonderful pain & chronic illness advocates I've met. They helped me find meaning at the lowest point in my life. I won't lie, it's been a struggle and I have had my share of setbacks too. Yet I know without question that pain medication was required in my case. It has made a serious difference to my overall health and it paved a way to my future too. I believe the day will come that I'll no longer need pain medication. It's something I'm now looking forward to!
It's hard to believe that I'm the same person who was once so desperately ill that I believed the only way to end my pain might be by ending my very life. I didn't want to die, but that's how severe the pain was back then. I wouldn't wish those dark days on anybody. That's why I'm so thankful I survived, and finally got the care I needed before it was too late.

Everyone should have the same sort of care I did: the best treatment protocol for each one of them as individuals. Look how it's turned out for me!

INTRACTABLE PAIN MUST BE MANAGED, LIKE ALL SERIOUS ILLNESSES — THESE ARE PATIENTS, NOT ADDICTS!
It's crucial to understand: Effective pain management for someone with Intractable Pain is as vital as care for any serious illness requiring long-term treatment. You'd never tell a diabetic that an arbitrary maximum units of insulin was all they were allowed to have. If that meant patients' diabetes being undertreated and dire medical consequences, including their eventual deaths, the world would be up in arms.

Why are pain patients any different? None of us asked for the pain, nor do we like having to take a prescription that's become so socially unacceptable. We're like diabetics. People in severe pain *depend* on medication for their survival. That medication happens to be opioids instead of insulin, but its an apt analogy for those with IP. What's more, the fact that it's pain medicine doesn't somehow make it wrong, just different.

The tragedy is that people like me are not addicts. This is, in fact, a very serious chronic medical condition. It isn't addiction we're living with, it's a massive amounts of pain.
Most people simply cannot understand what it's like to have pain that never ends, because it's incredibly rare. In a way, that's totally understandable. But to doubt someone you've known for years and were close to merely because they've got severe pain and require a serious form of treatment doesn't make sense to me.

I'd never doubt someone's suffering, because it's cruel. It's also emotionally devastating to be seriously ill but instead be thought of as crazy, a liar, attention-seeker or addict. Yet pain sufferers continue to be maligned by the media/public, their loved ones and even doctors.

THE LONG-TERM CONSEQUENCES OF THE CDC'S PAIN MED LIMITS
These judgments exist nowhere outside of pain management, so why must they exist at all? Why are people in pain being treated so differently, with such suspicion? The fact is, when the CDC's guidelines were released in 2016, the consequences were far-reaching and dire.

Countless patients have needlessly suffered and died. Many of these deaths have been due to the pain finally overtaking the body. Far more patients have chosen to end their immense pain via suicide.

Imagine being so ill that you were forced to make such a choice! This nightmarish situation continues to plague people just like me.

Choosing to battle misuse, abuse and addiction in this way wasn't worth the price to far too many in my community. We've already paid too much. It's not worth the devastation yet to be caused by continuing to stifle physicians' ability to treat pain either.

If I was able to, I'd love to speak to all "the powers that be" face-to-face. I'm living proof that with the proper dosage of pain medication, people who are severely chronically ill can and do get better. Our pain can lessen, and our lives improve!

The long-term impact on pain management is yet to be fully understood, but I know it will continue to cause serious systemic problems. For instance: How many medical school students will choose to specialize in pain management, knowing it could very well end their careers if they merely follow the Hippocratic oath? Not many.

THE END OF AN ERA: GREAT PAIN DOCTORS PUSHED OUT OF MEDICINE

I feel for anyone who's been diagnosed with Chronic or Intractable Pain since the CDC's guidelines were released in 2016. I know the sort of physicians they'll face, who'll tell them even more vigorously than was I told: you're wrong, you're crazy/lying, it's all in your head, etc. How many people survive the torture of physical pain in addition to a cold system that has no intention/ability to to treat their severe pain? Very few, and that's just plain wrong!

My situation isn't typical, I know that. It's a miracle that I've gotten back so much of what I believed to be lost forever. It's all thanks to amazing pain care. I am so grateful that I found the doctor that I did. I credit him with saving my life as well giving me the ability to return to work again — to be more like my old self against all odds.

Prior to the overzealous prosecution of caring physicians like Dr. Forest Tennant, doctors were far more willing and able to assist patients like me, the most seriously ill among us, who often only found the right doc after years of abuse and subpar care.
We came to these good physicians like beaten dogs who barely had enough life left in us to beg for help. We were all so mistreated even then that each of us came to believe our pain was a problem that couldn't be solved. Yet before the CDC guidelines, we were still able to find someone to provide us with real help when we needed it most!

To my dismay, Dr. Tennant and many like him were pushed out of their positions because of the CDC's guidelines, and the way the DEA chose to make examples of them. Dr. Tennant is a good man who didn't deserve a forced retirement in spite of no wrongdoing. The greater tragedy is the loss to patients who won't have anyone to help them find their way back to a meaningful life, or continue the one they'd already found. These patients won't learn, as I did, that with effective treatment, quite literally anything is possible.

THE RIPPLE EFFECT

It's more than just patients who lose because Dr. Forest Tennant was forced to retire. He taught countless other physicians, nurses and pharmacists how to understand & care for people with pain in a way too few do. For example: He knew there were objective signs of severe pain. How many people even know they exist? I do, because of Dr. Forest Tennant!

I believe wholeheartedly that without access to effective individualized treatment by physicians whose options aren't stifled by a system that doesn't understand pain, many more people with serious diagnoses will develop Intractable Pain. The difference is, no one will be there to help them find a way back to health. That means a lifetime of suffering needlessly, or else it means their eventual demise.

How incredibly sad it is to me that one particular type of patient is treated so differently than those with any other ailment!

If the CDC/DEA et al continue to force arbitrary rules onto everyone, unfortunately more and more people will end up with serious life-altering pain. It doesn't have to be this way!

Thanks to my doctor, I know that miracles can and do exist, even for the sickest among us. That'll only continue if those treating pain are equipped with the ability to make the necessary & appropriate decisions for the wellbeing of their patients. They must be able to utilize pain medication the right way, before their patients reach the end of their ropes and take their lives.

This is a possibility if and only if pain management can be practiced unfettered. Those outside the treatment setting have no business undermining patients' pain care protocols. They simply don't have the knowledge to be involved on that level.

That goes for the CDC, DEA, medical boards and insurance companies — along with anyone else who gets in the way of patients having effective care, and thus meaningful existence. I say this not as the average patient, but as someone whose medical knowledge and experience rivals that of many physicians. I worked in online continuing medical education (CME) for 9+ years. To this day, I read medical journals like any physician would.

Due to the severity of my condition, and the fact that I was at the mercy of a broken system like workers comp, my condition got far worse than it ever should've. I lived through the hell of both medical neglect and overtreatment. Sadly I know it's the workers compensation system that led to the severity of my illness, not the damage to my neck itself.

Because of my experience, I got an extensive education on how an overburdened system that's not designed for people with serious healthcare needs can quite literally cause permanent disability in someone like me. These days, treatment under the Affordable Care Act is much the same as it was for me when improper treatment left me with severe neurological impairment.

Since the CDC's 2016 guidelines were released, the powers that be have all but destroyed appropriate pain management. After this document was put forth, laws changed across the country and around the world. Restrictions to pain care seriously impacted people who rely on Medicare & Medicaid. Because of the changes to the pain-related care policies, effective pain management is far too difficult to access for the people with the least agency: those who are impoverished, over 65 or disabled. They deserve more protection against ineffectual treatment for acute health crises and long-term conditions, not less.

It's not just those patients who are suffering. Most HMO/PPO insurance plans have followed suit. These days, the options for any newly ill or injured person in pain are limited. Serious harm is being done to those with serious diagnoses who need real help.
The statistics show this to be the case. As time goes on, the number of preventable cases requiring longer and longer term pain management will grow exponentially. The end result is more Chronic and Intractable Pain patients — and thus, more serious disabilities that burden an already overburdened healthcare system.
The CDC all but provided an instruction manual for creating pain patients, not to mention causing needless suffering and death to existing chronically ill patients. That includes far too many dying via suicide, as I'm sure you have seen. This will end up killing the practice of pain management eventually. If you've been paying attention, you know: We're already well on our way to that possibility.

END THIS PROBLEM NOW, WHILE YOU STILL CAN
Maybe you don't need a pain management physician now, but what if one day you do? Will it be too late for you to find a doctor that's both willing and able to help you? I sincerely hope not. But it's possible.

Ask yourself: In this climate, who becomes a pain management physician today? More importantly, who will become one tomorrow?

Remember: These are human lives on the line. Everyone knows someone living with Chronic Pain. Yet for such a universal experience as pain, we've lost our way. It's time the powers that be returned the humanity and compassion to care for all patients, regardless of diagnosis. People who live with pain deserve that much, do they not? After all, the universal code of physicians is to "first do no harm."

Please don't jeopardize the future of an entire branch of medicine any further. Make the changes needed to continue treating people like me — people whose lives don't have to end because they have a serious injury or illness. It's crucial to roll back the damage done by the 2016 CDC guidelines before we all lose access to pain management forever.

All the best,
Heather Grace :)
Intractable Pain Patient & Patient Advocate

Standiford Helm, 11, M.D. Inc.
(Redacted)

June 20, 2022

Susan Cady, Associate Governmental Program Analyst Medical Board of California - Executive Office
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815-5401
via email: Susan.L.Cady@mbc.ca.gov

Re: Draft of updated 2014 Guidelines for Prescribing Controlled Substances for Pain.

Dear Ms. Cady,

I have been provided the Draft of the updated Guidelines by the Orange County Medical Association. Please find my comments below.

The revised Guidelines are an improvement on the 2014 Guidelines in that they are both updated and better organized than the 2014 document. The authors have clearly put a great deal of effort and skill into creating the current draft and we all owe them a debt of gratitude.

1. As an interventional pain management physician, I note that on page 6, "nerve block" is included under non-opioid treatment options. This inclusion is appropriate and consistent with HHS' Inter-Agency Task Force report, Pain Management: Best Practices. The phrase "nerve block" is unartful. The Board could consider using the categories used in the HHS report to describe "non-opioid therapeutic options:" "Medications, restorative therapies, interventional approaches, behavioral health approaches, and complementary and integrative health."

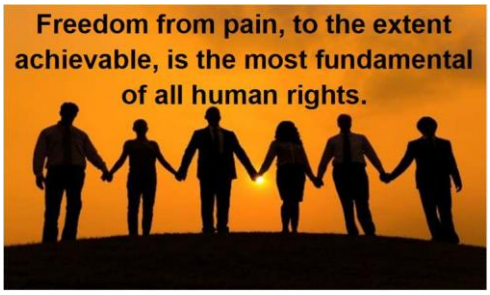
2. Page 7, Patient Consent. The new consent shown in the hyperlink is an improvement over the one currently used. Thank you.

3. Page 9, Initiating opioid therapy. The current language states, "If opioids are prescribed, they should be used in combination with non-opioid therapy such as pain psychology, exercise therapy, physical therapy, and/or non-opioid pharmacological therapy."

To keep the Guidelines internally consistent with the language on page 6, I suggest the following change: "If opioids are prescribed, they should be used in combination with non-opioid therapies such as pain psychology, exercise therapy, physical therapy, non-opioid pharmacological therapy, and/or interventional procedures."

Thank you for your consideration.

Standiford Helm, M.D.



Families for Intractable Pain Relief

June 30, 2022

Kristina D. Lawson, J.D., President

William Prasifka, J.D., Executive Director Members, Medical Board of California Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815

Re: Input for Interested Parties Meeting of the California Board of Medicine, July 14, 2022

Subject: **Ensure that California's Updated *Guidelines for Prescribing Controlled Substances for Pain* Will Enable Access to Medically Managed Care for Intractable Pain Patients**

Dear Ms. Lawson, Mr. Prasifka, and Members of the Medical Board of California

We write today to provide additional comments and specific recommended language for your consideration as the working group completes its project to update California's Guidelines for Prescribing Controlled Substances for Pain. We thank the Board for undertaking this effort, and we especially appreciate the opportunity to participate in the review of the draft and to speak about this at the upcoming Interested Parties meeting. These actions on your part fulfill commitments you have made to concerned stakeholders during the past year and we thank you for doing so. We also thank you for the shift in tone reflected in the draft. It's a welcome change from the attitudes apparent in the tone of most government documents released in recent years concerning the use of opioid pain medications.

We have attached a version of your draft that has our recommendations for additional or changed language incorporated; these are shown in red font. In some places within the document we have inserted "Notes to Board Members" that are shown in purple font. These notes are comments on various topics…things we wish to call to your attention but not intended to become part of the text. We expect we will have more comments and, if so, we will send them in advance of the meeting on July 14.

As stated in earlier correspondence, Families for Intractable Pain Relief (FIPR) is comprised primarily of former patients of Dr. Forest Tennant and family members of those patients. Dr. Tennant, who practiced in West Covina, CA, was the lead author of the Pain Patient's Bill of Rights that was passed by the California legislature and became law in the late 1990s. As a result of Dr. Tennant's continued research, technological advances in imaging, and other advances in medical science, he has continued to expand his knowledge of how to treat the most severe intractable pain and has pioneered use of the term Intractable Pain Syndrome to more accurately describe the illness suffered by the many patients he has treated.

With almost 50 years of experience treating intractable pain, Dr. Tennant's methods were based on his extraordinarily broad knowledge that enabled effective medical management of the most complex cases of intractable pain.

Unfortunately, very few physicians possess the knowledge and experience required to treat and manage those complex pain patients and the cardiovascular and endocrine complications that come with intractable pain.

We hope that by acknowledging intractable pain in the new guidelines, more physicians may become interested in working with and learning to effectively provide medical management of severe constant intractable pain.

Thank you for the opportunity.

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PREAMBLE

Protection of the public is the highest priority for the Medical Board of California (Board) in exercising its licensing, regulatory, and disciplinary functions. Within that function, the Board recognizes that principles of high-quality medical practice and California law ~~dictates~~ dictate that the people of California have access to appropriate, safe, and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life for patients who suffer from pain, particularly chronic pain.

The Guidelines for Prescribing Controlled Substances for Pain issued by the Board in 2014 were developed in response to concerns that prescription drug abuse was declared a nationwide epidemic and that drug overdoses had become a leading cause of accidental deaths. The intent was to provide guidance to physicians to improve outcomes in patient care and to prevent overdose deaths due to opioid use. The guidelines addressed the use of opioids with a focus on the long-term treatment of chronic pain.

In 2016, the Centers for Disease Control and Prevention (CDC) released guidelines which included recommendations for opioid prescribing by primary care clinicians 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 in order to improve patient outcomes (i.e., reduced pain and improved function), as well as reduce the number of patients who developed opioid use disorder, overdose, or experienced other prescription opioid-related adverse events.

While the number of overall opioid prescriptions in the United States had been declining, the release of the 2016 CDC Guideline furthered these declines but inadvertently contributed to patient harm. Several states designed and implemented new laws, regulations, and policies based on the guideline recommendations. In addition, many states' Medicaid programs, insurers, pharmacy benefit managers, and pharmacies used the CDC guidelines to create some opioid prescribing limits. CDC acknowledged that misinterpretation of their guidelines led to the unintended consequence of untreated and undertreated pain, serious withdrawal symptoms, worsening pain outcomes, psychological distress, overdose through use of illegal drugs, and suicidal ideation. As opioid prescribing continued to decline, the numbers of overdoses and opioid-related deaths continued to rise at a rapid rate.

The Board recognizes the need to ensure patient access to safe and effective pain management treatment and, at the same time, the Board also recognizes the need to support physicians providing treatment to this patient population. Consequently, the guidelines were updated to provide a framework for clinician use when developing a pain management treatment plan involving the use of opioids. The guidelines do not replace a physician's clinical judgment and individualized, patient-centered decision-making.

Since opioids are only one of many options to mitigate pain, the guidelines reinforce that opioid medication may not be the appropriate first line of treatment for a patient with chronic pain. Instead, a treatment plan is customized for each patient based on individual needs and vulnerabilities. The guidelines recommend a collaborative approach with the

patient to develop treatment goals and objectives that are reasonable and attainable. Collaboration is also required in the decision to alter or discontinue opioid therapy if the risks outweigh the benefits to the patient. A common thread running through these Guidelines is the need for individualized care based on the unique characteristics of each patient and the challenges they face. In this care environment, there will be a compelling need for physicians to clearly document the treatment and the rationale for it. Accordingly, proper record keeping will be paramount in this area of treatment and all physicians must take this into account in practice.

Although some of the recommendations cited in these guidelines might be appropriate for other types of pain, they are not meant for the treatment of patients in hospice or palliative care settings and are not in any way intended to limit treatment where improved function is not anticipated and pain relief is the primary goal.

UNDERSTANDING PAIN TERMINOLOGY

The diagnosis and treatment of pain is integral to the practice of medicine. To prescribe opioids safely and effectively, physicians must carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient.

Traditionally, pain has been classified by its duration. In this perspective, "acute" pain is relatively short duration, arises from obvious injury, and usually fades with healing. "Chronic" pain, in contrast, has been defined as lasting longer than would be anticipated for the usual course of a given condition, or pain that lasts longer than arbitrary cut-off times, such as three or six months.

For the purposes of these Guidelines, the following terms are defined as shown:

Acute pain is defined as pain lasting for less than one month. Subacute

pain is defined as pain lasting from one-three months. Chronic pain is

defined as pain lasting ~~greater~~ longer than three months.

End-of-life care is defined as care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home. **(NOTE TO BOARD MEMBERS: Suggest addition of definitions of hospice care and palliative care with focus on the distinction between them. See end of this section.)**

High Impact Chronic pain is defined as persistent pain with substantial restriction of life activities lasting 6 months or more.

Intractable pain is a state in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts. Intractable pain may be mild, moderate, or severe.

Intractable Pain with Multi-System Complications (or Intractable Pain Syndrome) is an excruciating, constant incurable pain state without remissions that involves life-threatening cardiovascular, endocrine and neurological system dysfunction and complications brought on by inadequate treatment of pain and failure to identify and treat the underlying cause of pain. Patients whose intractable pain has progressed to this level and complexity are at high risk of dying. A very small percentage of intractable pain patients (perhaps 1%) progress to this level, but they suffer the worst pain. They can and should be diagnosed and treated. Early diagnosis and treatment can prevent progression to this level.

(NOTE TO BOARD MEMBERS: Dr. Forest Tennant of West Covina, CA was the lead author of the Pain Patient's Bill of Rights that was passed by the California legislature and became law in the late 1990s. As a result of Dr. Tennant's continued research, technological advances in imaging, and other advances in medical science, he has pioneered use of the term Intractable Pain Syndrome to more accurately describe the illness suffered by the patients with severe constant pain whom he has treated.)

Long-term opioid therapy is defined as use of opioids on most days for greater than three months.

Physical dependence occurs because of physiological adaptations to exposure to a drug and is not the same as addiction. Someone who is physically dependent on medication will experience withdrawal symptoms when the use of the medicine is suddenly reduced or stopped or when an antagonist to the drug is administered. These symptoms can be minor or severe and can usually be managed medically or avoided by using a slow drug taper.

Tolerance is present when the same dose of a drug when given repeatedly produces a reduced biological response. Stated another way, it takes a higher dose of the drug to achieve the same level of response achieved initially.

Addiction is a primary, chronic disease of brain reward, motivation, memory, and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social, and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

Opioid Use Disorder is defined in the DSM-5 as a problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two DSM- 5 criteria occurring within a 12-month period. It is important to note that opioid use disorder exists on a continuum of severity and the severity distinction has treatment implications. A scale for assigning severity exists and is based upon the number of criteria that have been met (mild, moderate, severe).

Hospice Care focuses on the pain, symptoms, and stress of serious illness during the terminal phase. Hospice care is for any individual with a serious illness whose life expectancy is measured in months, not years. Medicare's Hospice Program provides benefits for in-home care as well as care in residential facilities. Persons covered by Medicare may be eligible for the program if their life expectancy is 6 months or less if the disease runs its natural course. These guidelines do not apply to hospice care.

Palliative Care is specialized medical care for people living with serious incurable illness that have **not** been determined to be in the terminal phase of their illness. Palliative care can be provided at any stage of illness once it is determined to be incurable. It focuses on the pain, symptoms and stress of serious incurable illness most often as an adjunct to continuing curative care modalities. The goals are to enable effective pain management, to enable improved function to whatever extent is feasible, and to improve quality of life for both the patient and the family.

RECOMMENDED PRACTICES FOR THE MANAGEMENT OF PATIENTS WITH PAIN

The following practices should be incorporated into the care and management of a patient being treated for pain with opioid analgesics.

PATIENT EVALUATION AND RISK STRATIFICATION

When considering long-term use of opioids for chronic, non-cancer pain, careful and thorough patient assessment is critical. Assessment of the patient's pain and risk ~~stratification~~ status is a key element to mitigate potentially adverse consequences of opioid prescribing. The nature and extent of the clinical assessment depends on the type of pain and the context in which it occurs. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning. In the sections below, patient reported outcome (PRO) tools are provided as examples. Recognizing that improvements in PROs as science advances **(incomplete clause…is this intended to refer to actual patient outcomes or improved PRO tools?)**, the recommendations are not meant to be prescriptive. Other PRO~~s~~ tools may be used to assess and longitudinally assess and track the patient's progress over time. A thorough patient assessment includes but is not limited to:

- Completing a medical history and physical exam

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use. A comprehensive history can also include the "4 A's" (analgesia, adverse effects, activity, and aberrancies) as part of the documentation of opioid response. Screening tools for pain and/or function include but are not limited to:

- Pain Intensity and Interference (pain scale)
- Brief Pain Inventory – Short Form (BPI-SF)
- PROMIS Pain Interference
- PROMIS Function tests are available through HealthMeasures in both pdf and digital formats.

Patients can also be screened for depression and other mental health disorders, as part of the risk evaluation. Psychological distress frequently interferes with improvement of pain and function in patients with chronic pain.

- Assessment for opioid misuse behavior

Assessment of the patient's personal and family history of alcohol or drug use and relative risk for medication misuse also should be part of the initial evaluation. Ideally this should 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) for criteria for diagnosing Opioid Use Disorder.

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.

Common Risk Mitigation tools that can be considered for use include:

- TAPS
- SOAPP-R
- CRAFFT for adolescents

Note: Although the above-listed assessment tools are well-established with proven effectiveness, physicians should be aware that some patients may anticipate how to respond in order to attain a "reduced" risk level.

- **Establishing a diagnosis and medical necessity**

A diagnosis should be reached through a review of past medical records, laboratory studies, imaging studies, etc. and ordering new ones, if previous studies are outdated. Information provided by the patient is a necessary but an incomplete part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Some patients are not reliable historians, so it is best to request records directly from the other providers. Patients who have suffered from pain for a long time may have helpful records that are otherwise unavailable.

- Exploring non-opioid therapeutic options.

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~~ safe and ~~more~~ effective therapies have proven inadequate. Determining if potential benefits of opioid analgesics outweigh the potential risks is key. Resources that can be consulted include:

- Non-Opioid Treatments for Chronic Pain - Health and Human Services
- Non-Opioid Treatments -American Society of Anesthesiologists

With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own risk-benefit analysis coupled with their comfort level in prescribing such medications and the resources for

patient support that are available in the family and community. The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation, assessment, use of mitigation tools, and a discussion of risk/benefits and alternatives with patients. Patients should not be expected or required to repeat treatments previously tried and failed.

TREATMENT PLAN AND OBJECTIVES

After conducting a thorough Patient Evaluation/Risk Stratification assessment and determining that the use of opioid analgesics is indicated, the physician and the patient should develop treatment goals and objectives together when starting an opioid trial. The goal of pain treatment should include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Pain relief is important but is difficult to measure objectively. Therefore, it cannot be the primary indicator to assess the success of the treatment. *Effective pain relief improves functioning.* Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient. An "exit strategy" should be included in the treatment plan for all patients receiving opioids at the outset of treatment.

The plan should also document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered. Because pain management in patients with a history of substance use disorder can be complex, in such cases consider consulting with a specialist in addiction medicine. If the patient has a current history of substance use disorder, communicate with the patient's substance use disorder treatment provider.

A thorough attempt to treat pain with opioids often requires upward dose titration in measured steps to determine whether opioid medications can be effective. An opioid trial should not be abandoned if the initial dose attempted is not effective, provided there are no significant adverse effects. After an appropriate opioid trial, treatment efficacy should be reassessed, and opioids should only be continued if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety**.** If the opioid trial fails, meaning it does not achieve the desired pain control or functional outcome, the opioid should be discontinued as other modalities are explored. That discontinuation may involve a compassionate, slow taper depending on the patient and circumstances.
(See Note about improvement in function and functional assessment under Cancer Pain/End-of-Life Pain.)

Patient Consent

When considering long-term use of opioids and periodically during opioid therapy, the physician should discuss the risks and benefits of the treatment plan with the patient and persons designated by the patient, if applicable. A sample Informed Consent form is available through the National Institute on Drug Abuse. For convenience, patient consent and a pain management agreement can be combined into one document.

If the patient is a minor, the law requires that the risks be explained to both the minor patient and the patient's parent/guardian before dispensing or issuing the first prescription. The patient/parent must be advised of: 1) the risks of addiction and overdose associated with the use of opioids, 2) the increased risk of addiction to an opioid if the patient is suffering from both mental and substance abuse disorders and, 3) the increased risk of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.

The patient (and family members, if appropriate) should also be counseled on safe ways to store and dispose of medications.

Pain Management Agreements

Use of a pain management agreement is 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:

- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (e.g., by using more medication than prescribed or using the opioid in combination with alcohol or other substances; not storing medications in a secure location; and ~~safe disposal~~ failing to safely dispose of any unused medication to prevent misuse by other household members).
- The patient's responsibility for following instructions given for safe opioid medication use by their clinician.
- The patient's responsibility to obtain their prescribed opioids from only one physician or practice. Patient's agreement to obtain their medication from one pharmacy provided that the pharmacy is able to dispense the prescribed monthly supply.
- The patient's agreement to periodic drug testing (blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills, if appropriate and in accordance with the patient's pain management agreement.

Examples of pain management agreements include:

- Sample Patient Agreement
- Patient Pain Medication Agreement and Consent
- Treatment Plan Using Prescription Opioids

INITIATING OPIOID TRIAL

Safer alternative treatments should be considered before initiating opioid therapy for chronic pain. Non-opioid therapies are preferred as first-line treatments for chronic pain (including non-pharmacologic therapy). If opioids are prescribed, they should be used in combination with non-opioid therapy such as pain psychology, exercise therapy, physical therapy and/or non-opioid pharmacologic therapy as appropriate for individual patients. The World Health Organization 3-Step Analgesic Ladder, as originally conceived, provides a useful tool to guide the sequence of treatments attempted. Recent attempts to modify the ladder concept have added alternative treatments, many of which are not covered by health insurance, and interventional treatments which may be helpful to some patients. However, these modified ladders in some cases may understate the importance and value of opioid pain medications in treating moderate and severe pain.
Also, patients should not be required to engage again in alternative treatments that caused them harm or for which the financial cost exceeded benefits gained.

California law requires that physicians review a Patient Activity Report (PAR) generated from CURES (California's prescription monitoring program) on each patient within 24 hours before prescribing or ordering a controlled substance for the first time, with some limited exceptions.

Evaluate the benefit and harm within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Continuation of opioid therapy after an appropriate trial should be based on outcomes such as: making progress toward functional goals; presence and nature of side effects; pain status; and a lack of evidence of medication misuse or diversion. Patients with no, or modest, previous opioid exposure should be started at the lowest appropriate initial dosage of a short-acting opioid and titrated upward, if needed, to decrease the risk of adverse effects. The selection of a starting dose and manner of titration are clinical decisions made on a case-by-case basis because of the many variables involved. Some patients, such as older persons or those with co-morbidities, may require an even more cautious therapy initiation. Short-acting opioids are usually safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of overdose from drug accumulation. The general approach is to "start low and go slow" when initiating opioid therapy for opioid-naïve patients.

~~**Morphine Equivalent Dose (MED)**~~

(NOTE TO BOARD MEMBERS: Many have questioned the validity and usefulness of the MED concept and the unfortunate outcomes of its inclusion in Federal and state prescribing guidelines, payer policies, and law enforcement decision-making processes. We recommend deletion of this section as written. If more needs to be said, additional language can be added to the preceding section. We endorse the approach taken in the following extract from the current FSMB Opioid Guidelines which reads as follows:

"As noted by the FDA, when initiating opioid therapy for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, it is highly recommended that the lowest dose possible be given, beginning with a short acting opioid and/or rotating to a long acting/extended release, if indicated."

(NOTE TO BOARD MEMBERS cont.) It is our opinion that physicians and patients will ultimately be better served by deleting references to MED in this update to California's Guidelines for Prescribing Controlled Substances for Pain. We strongly suggest deleting this section as written and replacing it with such common-sense language as shown above. If you leave in this document such words as "use extra precautions when increasing to ≥ 50 MME per day" and "doses ≥ 90 MMEs should either be avoided or carefully justified", you will be signaling to physicians that they better *continue to observe those CDC numbers*, *get out of pain care*, and/or certainly *don't plan to come back to pain care* if they've already left. There is no credible evidence to support the use of those specific numbers as guides or thresholds. They will continue to be weaponized against physicians, and patients will continue to be left without care. Some Board Members stated in the May 19-20, 2022 Quarterly Board Meeting that you recognize the urgent need for physicians to return to the practice of pain care, and that you will take action to encourage physicians to do so. If that is your true intent, delete MME numbers from this document and encourage other organizational elements within the California state government to disregard MME numbers.

In addition, we recommend adding this statement: The Medical Board of California does not support consideration of dosing thresholds in prescribing decisions, payer policies, investigations, or law enforcement decision-making processes.)

~~Calculating the total daily dose of opioids helps identify 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. While some clinicians have questioned the conceptual validity of MED because of its use as a tool in prescribing guideline development and the lack of a universally accepted opioid-conversion method, this concept remains in common use. CDC has developed a fact sheet titled Calculating Total Daily Dose of Opioids. After calculating the total daily dosage, CDC recommends physicians use extra precautions when increasing to ≥ 50 MME per day such as monitor and assess pain and function more frequently; discuss reducing the dose or tapering and discontinuing opioids if benefits do not outweigh harms and consider offering naloxone. Doses ≥ 90 MMEs should either be avoided or carefully justified.~~

California law ~~also~~ requires that a prescription for naloxone be offered each time the patient is seen when the dosage is ≥ 90 MMEs per day.

COUNSELING PATIENTS ON OVERDOSE RISK AND RESPONSE

It is important to educate patients and family/caregivers about the danger signs of respiratory depression or overdose while on opioids and how to respond to the potential medical emergency. Family/caregivers should know to summon medical help immediately if a person demonstrates any of the following signs:

Unconsciousness or inability to awaken.

- Slow or shallow breathing or breathing difficulty such as choking sounds or a gurgling/snoring noise from a person who cannot be awakened.
- Fingernails or lips turning blue/purple.

Family/caregivers should also be educated on the use of naloxone and how to administer it, if necessary. Prescribers are required to offer a prescription for naloxone, or another drug

approved by the FDA to reverse the effects of opioids, to a patient who is receiving 90 MME or higher per day, receiving concurrent benzodiazepines, or at risk of overdose. Pharmacists are also authorized to prescribe and dispense naloxone to patients or family/caregivers at risk of experiencing or witnessing an opioid overdose.

SAMHSA's Opioid Overdose Toolkit and Prescribe to Prevent ~~contains~~ **contain** educational materials relating to overdose prevention and management as well as patient education material ~~and~~ videos on the use of naloxone. A brochure titled Opioid Safety and How to Use Naloxone also provides helpful information for family/caregivers.

ONGOING PATIENT ASSESSMENT

When a trial of an opioid medication has been completed and a decision is made to continue opioid medication ~~is started~~, regular review and monitoring should be undertaken for the duration of treatment. Within one-four weeks after starting opioid therapy, and at least every three months, evaluate benefits and harms with the patient.

- Assess the patient's pain and function regularly.
- Discuss patient-centered goals and improvements in function (such as returning to work and recreational activities) and assess pain using validated instruments such as the three-item PEG Assessment Scale, the Pain Assessment Documentation Tool, or PROMIS Pain Interference.
- Evaluate for factors that could increase the patient's risk for harm from opioid therapy such as: personal or family history of substance use disorder, mental health conditions (e.g., anxiety or depression), pregnancy, age 65 or older, chronic obstructive pulmonary disease or other underlying respiratory conditions or renal or hepatic insufficiency.
- Conduct ~~regular~~ urine drug testing and review CURES reports as described elsewhere in this document.
- Observe patient for signs of over-sedation or overdose risk and consider tapering dose to a lower dose if identified.
- Assess patient for signs of opioid use disorder using Diagnostic and Statistical Manual of Mental Disorders (5^{th} Edition) criteria. It is important to note that opioid use disorder exists on a continuum of severity and the severity distinction has treatment implications. A scale for assigning severity exists and is based upon the number of criteria that have been met (mild, moderate, severe). If the criteria for opioid use disorder are met, arrange for patient to be evaluated by a provider experienced in treating OUD.
- Ask the patient about their concerns and determine any harm they may be experiencing such as: nausea or constipation, feeling sedated or confused, breathing interruptions during sleep, taking or craving more opioids than prescribed or difficulty controlling use.

If the patient does not have an improvement in pain and function, consider reducing dose or tapering and discontinuing opioids. The decision to continue opioids must be based on a careful assessment between the physician and patient when improvements in both pain and function outweigh the harms.

COMPLIANCE MONITORING

The physician must decide whether to revise or augment a pain management agreement and/or treatment plan if the patient's progress is unsatisfactory. If it is suspected that a patient may be misusing or diverting prescribed medications, or using illicit drugs, a careful re-assessment of the treatment plan must be undertaken. A patient's failure to adhere to a pain management agreement is not necessarily proof of misuse or diversion. Failure to comply may be the consequence of inadequate pain relief, confusion regarding the prescription, an untreated or undertreated underlying substance use disorder, a language barrier, or economic concerns. A physician should arrange for an in-person meeting to have a non-judgmental conversation to clarify their concerns. If misuse is confirmed, consultation with an addiction medicine specialist or mental health specialist trained in substance use disorders and/or referral to a substance use disorder treatment program that provides medication-assisted therapy (MAT) should be facilitated. Physicians who prescribe long-term opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives. Refer to the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition **(DSM-5)** for criteria for diagnosing Opioid Use Disorder.

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors usually require a firmer, immediate response. The degree to which the patient has breached the pain agreement and/or the presence of criminal activity should govern the physician's response. Although an immediate face-to-face meeting with the patient to re-evaluate the treatment plan may be appropriate, in some instances it may be necessary to taper opioid therapy and/or terminate the physician patient relationship. In situations where the patient has engaged in prescription forgery, prescription theft or assaultive behaviors directed towards the physician or staff, the physician is strongly encouraged to contact the police/Drug Enforcement Agency (DEA).

For other criminal behaviors, the physician is encouraged to contact legal counsel to determine whether it is appropriate to report to law enforcement. Failing to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrest and incarceration, or even death.

The following strategies should be used to monitor compliance with the pain management agreement or to identify potential issues with the treatment plan. Remember, aberrancies in any of the strategies described below does not necessarily equate to a substance use disorder and needs to be analyzed along with the entire patient presentation.

CURES Reports

CURES is a database that tracks all controlled substance prescriptions dispensed in California. All licensed physicians must register for access to CURES and generate a Patient Activity Report (PAR) on each patient within 24 hours before prescribing or ordering a controlled substance for the first time, with some limited exceptions. It is recommended that a PAR be generated and reviewed at least every 3-6 months as part of the physician's ongoing patient assessment if controlled substances remain a part of the patient's treatment plan. California law requires that a PAR be generated on each patient at least every 6 months. CURES also alerts prescribers to patients with multiple prescribers, high-dose opioid prescriptions, concomitant opioids and benzodiazepines, and daily opioids over 90 days.

Patients should not be dismissed from care based solely on information from the CURES database. Instead, use the opportunity to discuss any areas of concern with the patient and emphasize concerns about patient safety. Attempt to confirm that the information in the PAR is correct. Check for potential data entry errors, use of a nickname or maiden name, or possible identity theft to obtain prescriptions.

Urine Drug Testing

~~**All**~~ It has been generally accepted that patients on long-term opioid therapy should have periodic urine drug tests (UDT). Physicians should use urine drug testing before starting opioid therapy and may consider urine drug testing at least annually using the risk assessment to guide UDT screening frequency. Long-term stable patients may not require frequent testing. Consider more frequent testing for higher risk individuals or at the time of aberrant behavior. Clinical judgment should guide frequency of testing, keeping in mind that UDTs are often inaccurate, some are costly, and they are sometimes not covered by insurance. UDT results have also been used by physicians as an excuse to discharge patients. It should be understood that over-reliance on UDTs may serve as a barrier to physician/patient relationships as the requirement for such testing is often interpreted by patients to mean that physicians don't trust them. Properly performed urine drug testing involves two steps: an initial screening test followed by confirmatory testing for substances with positive screening results. Confirmatory testing is also needed in situations with an unexpected negative result as a means of distinguishing a false negative from a true negative. Patients should not be assumed guilty of wrongdoing until proven innocent.

If unexpected results occur after ordering a UDT, remember that the focus is to improve patient safety. Have a plan in place for communicating results and do not dismiss patients from care based solely on UDT results. CDC developed a fact sheet on urine drug testing with tips for discussing the use of UDTs with patients as well as the types and limitations of UDTs. Additional information and recommendations are also available from the American Family Physician in an article entitled Urine Drug Tests: Ordering and Interpretation.

Pill Counting

Periodic pill counting can be a useful strategy to confirm medication adherence and to minimize diversion (selling, sharing, or giving away medications) in the case of new patients or patients whose reliability is in question. The CURES report only gives total dispensing numbers but day to day or week to week usage can be monitored with pill counts when needed. However, like urine drug testing, pill counting communicates distrust to the patient and can damage the physician/patient relationship. Pill counting may not be necessary or desirable for long-term stable patients. If used at all, pill counting should be approached with sensitivity and caution. Patients should not be assumed guilty of wrongdoing until proven innocent.

(NOTE TO BOARD MEMBERS: Optimal opioid prescribing for some long-term patients with severe pain has in the past sometimes involved prescribing both an extended release opioid and a short-acting opioid for breakthrough pain. Short-acting breakthrough pain medications could most effectively be used if the patient had some flexibility permitted by the stated dosing on the prescription…for example, "take 1-2 tablets every 4-6 hours." It is our impression that giving the patient such

flexibility is now not allowed or at least frowned upon, and that is very unfortunate. This kind of flexible dosing encourages the patient to engage in actively managing his pain and making his own decision not to take 2 tablets if 1 tablet will suffice for a particular dose. In today's treatment environment, patients probably aren't given such flexibility and if they decide to take 1 tablet when the prescription says take 2, they must put the extra pill away to keep the pill counters satisfied. This establishes a "play the game" situation that damages the physician/patient relationship.

Also, regulators should be advised that pill-counting is not only undesirable from the relationship standpoint, it is ridiculous and unnecessary in the case of long-term severe intractable pain patients. *These patients would never sell or give away their pain medications!*)

DISCONTINUING OPIOID THERAPY

Discontinuing or tapering of opioid therapy may be required for many reasons and ideally, an "exit strategy" should be included in the treatment plan for all patients receiving opioids at the outset of treatment. Reasons for discontinuing opioids may include:

- Resolution or healing of the painful condition
- Patient experiences side effects that diminish quality of life or impair function
- Failure to achieve anticipated pain relief or functional improvement (after ensuring that this failure is not the result of inadequate treatment)
- Patient has been treated with opioids for a prolonged period (e.g., years) and current benefit-risk balance is unclear **(NOTE TO BOARD MEMBERS: The meaning of this bullet is unclear. If a patient has documented intractable pain, has achieved good pain control and regained significant function, and seems to be doing well, physicians should not assume that the patient doesn't need the opioid pain medication. Once the optimal treatment regimen has been identified and implemented, it is not realistic to expect to see function continue to improve indefinitely. Perhaps the accurate conclusion is that the patient has achieved optimal treatment that should be regarded as effective long-term maintenance.)**
- Patient experiences an overdose or other serious event (e.g., leading to hospitalization or injury)
- Evidence of non-medical or opioid misuse
- Failure to comply with pain management agreement and/or urine drug screen monitoring
- Exhibition of drug-seeking behaviors (after ensuring this behavior is not the result of inadequate treatment) or diversion

If tapering is determined to be the appropriate course of action, the rate of tapering should be individualized based on the clinical situation of the patient. It should be noted that abruptly stopping opioid therapy has been shown to increase illicit opioid use, emergency medical care utilization, mental health crises, and death from overdose and suicide. Tapers can be completed over several months to years depending on the opioid dosage and should be individualized based on patient goals and concerns. Longer durations of previous opioid therapy might require longer tapers.

A slower taper will produce fewer unpleasant symptoms and signs of opioid withdrawal (e.g., drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection). The symptoms of withdrawal can be more difficult for those diagnosed with an opioid use disorder. The severity of withdrawal symptoms can be assessed and measured using the Clinical Opioid Withdrawal Scale (COWS). Medications can be used to manage opiate withdrawal symptoms of nausea, vomiting, diarrhea, anxiety, and vasomotor complaints. Commonly used medications include clonidine, hydroxyzine, loperamide, and others.

Tapers of approximately 10% per month or slower are likely to be better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., a year or longer). ***Tapers might have to be paused and restarted again but may be considered successful as long as the patient is making progress.*** Health and Human Services (HHS) has produced a guide with tapering strategies titled the Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long Term Opioid Analgesics.

(NOTE TO BOARD MEMBERS: Tapering needs to be addressed in this document, but we should keep in mind that the goal should be successful treatment of the patient, not successful tapering.)

Patients with unanticipated challenges to tapering, such as inability to make progress in tapering despite opioid-related harm, might have undiagnosed opioid use disorder. **(NOTE TO BOARD MEMBERS: Has opioid-related harm been accurately identified? Is it perhaps just as likely that the patient is suffering from a resumption of higher pain levels?)** Patients experiencing such challenges should be assessed for opioid use disorder using Diagnostic and Statistical Manual of Mental Disorders (5th Edition) criteria. If the criteria for opioid use disorder are met, consider whether the use of buprenorphine would be appropriate. Buprenorphine has been shown to be a safe treatment for pain management and OUD and is FDA-approved for both conditions. **(NOTE TO BOARD MEMBERS: Buprenorphine is unlikely to be effective for long-term severe intractable pain patients.)** Buprenorphine reduces craving, withdrawal, and overdose risk, has low potential for misuse and diversion, and increases retention in care. Physicians can prescribe buprenorphine for opioid use disorder for up to 30 patients in an office-based setting after requesting a waiver from SAMHSA with no training required.

Physicians unable to provide treatment themselves should arrange for the patient to receive treatment from a substance use disorder treatment specialist, such as an office based buprenorphine or naltrexone treatment provider or an opioid treatment program certified by SAMHSA.

Physicians should not dismiss patients from their practice **solely** because of opioid use disorder as this can adversely affect patient safety and could potentially represent patient abandonment.

The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate.

If the decision is made to either terminate opioid therapy or completely terminate care, it is recommended that the patient be notified in writing **at least 30 days** in advance.

Physicians can be held accountable for patient abandonment if medical care is discontinued without allowing adequate provision for subsequent care. The written notification to the patient should include tapering instructions and a bridging prescription (if appropriate) and options to locate alternative sources of medical care. Patients can be referred to other physicians by name, to the patient's insurance company for a list of providers, the medical society's referral service or provided with information about local treatment facilities, methadone maintenance programs or local buprenorphine treatment providers. Examples of patient termination letters are provided in Appendix 1. A copy of the termination letter should be retained in the patient's chart.

Physicians may want to also review their health plan contracts for guidance on terminating and/or reassigning patients to another provider.

If a patient is known to be abusing a medication, initiating an opioid wean may be appropriate. Consultation with an attorney and/or one's malpractice insurance carrier may be prudent in such cases. Conversely, if a patient has been found to be diverting the medication, there is no requirement to provide additional prescriptions, tapering instructions or advance notice of termination beyond the standard 15 days.

(NOTE TO BOARD MEMBERS: As stated, it is clearly appropriate to address discontinuing opioids, tapering, and terminating patients in this document, the Guidelines for Prescribing Controlled Substances for Pain. However, so much content is devoted to these topics that those sections seem to compete with the real goals of providing safe and effective pain management, aiding restoration of function, and improving quality of life for pain patients and families. Could the sections that address discontinuing opioids, tapering, and terminating patients be moved to an appendix so that they are readily available but not appearing to compete with coverage of how to use opioids properly to achieve the goals?)

MEDICAL RECORDS

The decision to prescribe controlled substances for pain is a clinical decision made by the physician based on the unique needs of the individual patient. The rationale for each prescribing decision must be documented in the patient's medical record. If a complaint is filed with the Medical Board regarding a physician's care and treatment, peer expert review will be sought by the Board. The expert reviewer will consider the totality of circumstances surrounding the physician's prescribing practice through a review of the documentation contained in the patient's medical record. The expert reviewer will attempt to identify whether the physician reached a *clear medical diagnosis* and documented a medical indication for any controlled substances prescribed. A *clear medical diagnosis* is determined by obtaining objective evidence that includes documenting a complete medical history, including information regarding the beginning of the condition, location, specific symptoms and duration of the condition, exacerbating or palliative triggers and the efficacy of prior treatments; obtaining and reviewing prior medical records and imaging studies; performing and documenting a robust physical examination, particularly of the affected part of the patient's body and the patient's history of substance abuse.

(NOTE TO BOARD MEMBERS: If expert reviewers are assigned to review care provided by a physician who specializes in treatment of severe intractable pain with multi-system complications, expert reviewers must themselves be fully knowledgeable of such pain

conditions and the considerations involved in caring for such patients.)

California law requires that physicians maintain adequate and accurate medical records. An adequate medical record includes, but is not limited to, the documentation of the:

- patient's medical and pain history;
- notes on relevant history from other providers and evaluations or consultations with specialists;
- results of the current pain and risk assessment, including any screening instrument(s) used;
- results of the physical examination and any laboratory tests or imaging studies ordered by the physician;
- results of CURES and urine drug screens;
- treatments provided, including medications prescribed or administered with the date, type, dose and quantity indicated;
- results of ongoing monitoring of the patient's progress (or lack of progress) in terms of pain management and functional improvement;
- instructions given to the patient, including discussions of risks and benefits with the patient and any significant others;
- patient consent and the pain management agreement;
- information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors.

Appendix 2 reflects an example of a medical record documenting a clinician's initial assessment and treatment of a patient being seen for chronic pain. This example can also be accessed through the Center for Innovation in Academic Detailing on Opioids (CIAO) in a document titled Opioids for Chronic Pain Documentation Suggestions.

SUPERVISING ALLIED HEALTH PROFESSIONALS

Physicians may work in an integrated practice with allied health professionals and be called upon to provide supervision. Below are the regulatory requirements for each along with the parameters for prescribing controlled substances.

Physician Assistants (PA's) provide services pursuant to a practice agreement under physician supervision. The supervising physician must be available either in person or by telephone or other electronic communication when the PA is caring for patients. PAs are authorized to order controlled substances (Schedules 11-V) that have been agreed upon in the practice agreement and are consistent with the PA's education or for which clinical competency has been established and maintained. Orders for Schedule II or Ill controlled substances must be in defined in the practice agreement or in a patient-specific order approved by the treating or supervising physician.

Nurse Practitioners (NPs) who have *completed* a *transition to practice,* and meet other requirements, are authorized to practice independently, and prescribe, order, or administer controlled substances, pursuant to Business and Professions Code section 2837.103. NPs who do not complete the transition to practice continue to work under standardized procedures with an overseeing physician. Orders for Schedule II or Ill controlled substances must be in accordance with patient-specific protocols approved by the treating/supervising physician. Protocols for Schedule II substances must address the diagnosis of illness, injury, or condition for which the substance is to be furnished.

SPECIAL PATIENT POPULATIONS

Below are treatment considerations for differing patient populations or scenarios and are intended to provide additional guidance in prescribing opioids when appropriate.

Acute Pain

It is important to emphasize that numerous recommendations in these guidelines may not be relevant for the physician treating a patient for acute pain. For example, a primary care physician treating a patient who presents with a medical condition manifested by objective signs (e.g., a fractured ulna or kidney stones discernible with imaging studies) would not necessarily need to undertake an opioid trial, perform a complete psychological assessment, utilize a pain management agreement, etc. Physicians should, however, consider any underlying or co-occurring disorders or conditions while assessing risks of opioid therapy. When implementing an acute pain management plan, a standardized approach that starts with non- pharmacological and non-opioid medications and proceeds with stepwise escalation based on pain trajectory and response to treatment is recommended. Non opioid options such as peripheral nerve blocks and neuraxial analgesia are a reasonable and effective option for surgical pain control. The CURES database should be consulted to ensure a new opioid prescription will not contribute to cumulative opioid dosages or medication combinations that put the patient at risk for overdose. Naloxone should be offered if the patient has risk factors for opioid overdose. As more clinical guidance is required (especially in complex patients such as substance use disorder, opioid tolerance), a

consultation with a pain specialist may be indicated.

Patients prescribed methadone or buprenorphine for treatment of a substance use disorder may need relief from acute and/or chronic pain, beyond that provided by their maintenance medication. For more information on pain relief for persons on methadone or buprenorphine, see Pain Control in Patients on Buprenorphine, Methadone or Naltrexone.

Cancer Pain/End-of-Life Pain

In the 1990's, the Pain Patient's Bill of Rights and the Intractable Pain Treatment Act were created to ensure patients received adequate pain medication and to protect physicians from being disciplined solely because of the amounts of controlled substances prescribed or administered. It was recognized that inadequate treatment of pain originating from cancer or noncancerous conditions was a significant health problem and patients suffering from severe chronic intractable pain should have access to proper treatment for their pain.

The Pain Patient's Bill of Rights indicates that patients suffering from severe chronic intractable pain have the option to request or reject the use of any or all modalities to relieve pain and choose opiate medications without first having to submit to an invasive medical procedure if the physician acts in conformance with the Intractable Pain Treatment Act. A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve the patient's pain if that prescribing conforms with the Business and Professions Code. Finally, a physician may refuse to prescribe opiate medications to a patient with severe chronic intractable pain but must inform the patient that there are physicians who will treat pain using opiates.

California law also eliminated the need for security prescription pads or e-prescriptions when prescribing pain relief for the terminally ill. "Terminally ill" was defined as the patient is suffering from an incurable and irreversible illness that will bring about death within one year if the illness takes its normal course and the treatment is for pain control and/or symptom management rather than to cure the illness. Under these circumstances, a prescription must only contain the patient's name, the name, quantity of drug and directions for use and the prescriber's signature, date, and the phrase "11159.2 exemption".

The Guidelines for Prescribing Controlled Substances for Pain are not meant to be **used in the treatment of patients with "end of life" or intractable pain and are not intended to limit treatment where significant improvement in function is not anticipated and pain relief is the primary goal.** However, given the advancements in diagnosis and treatment of cancer, more patients are surviving cancer but are left with chronic pain resulting from their exposure to cancer treatments. The guidelines are applicable to cancer survivors being treated for chronic pain **if their pain is well-managed, they do not have multi-system complications, and they are not otherwise impaired by their cancer experience**.

(NOTE TO BOARD MEMBERS: Improvement in function is a relative term. Improved function for a chronic pain patient whose moderate to severe pain is well-managed with medication and who is not afflicted with complications may mean being able to resume full-time employment after being out

of the workforce. Improved function for intractable pain patients with multi-system complications may, on the other hand, mean feeling well enough to go out to dinner with friends or to ride the garden tractor for an hour or two to mow the yard. We believe that improvement in function should be a goal for treatment for any patient with effective pain control, even those with intractable pain with complications, but assessment of improvement in function must be approached differently for these patients and their care should not be limited by these guidelines. Physicians should keep in mind that standardized assessment tools may or may not provide the best understanding of function improvement. A conversation with the patient and family member may reveal that the patient has been able to resume activities not listed on an available assessment tool, but that make a meaningful difference in the life of the patient and his/her family. Such patient and family reports have merit and should be documented in the patient's chart.)

Emergency Departments/Urgent Care Clinics

Treating patients for acute pain in an emergency department (ED) or urgent care setting presents challenges in that often there is limited ability to procure adequate patient history from a primary care physician. All physicians have access to CURES and must generate a Patient Activity Report (PAR) before prescribing a controlled substance to a patient for the first time. While there is an exception for physicians in an ED of an acute care hospital when the prescription does not exceed a non-refillable 7-day supply, a PAR will provide some patient history information that is otherwise not available. Physicians practicing in an urgent care setting are not exempt from the requirement to consult CURES before prescribing a controlled substance.

The American College of Emergency Physicians notes that opioid prescribing in the ED, even when limited to short-acting, low-potency medications for a few days of therapy, is not risk free. Therefore, opioid prescribing from the ED for an acute painful condition should be reserved for patients for whom there is a need for pain relief and alternative therapies are expected to be ineffective or are contraindicated. In those cases, 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.

A coalition of stakeholders from Los Angeles County developed a toolkit titled Safe Pain Medicine Prescribing in Emergency Departments and Urgent Care Centers" with the goal of establishing safe norms surrounding the use of pain medications. Patient materials, handouts and clinical practice guidelines are contained in this toolkit.

Inherited/Legacy Patients

Patients started on long-term opioid therapy can find themselves suddenly without a physician either due to physician retirement, state or federal action, or some other cause. Given the national shortage in pain management clinicians, it is anticipated that patients taking long-term opioids for their chronic pain may have difficulty finding a new clinician and primary care physicians may inherit these patients. Abrupt cessation of opioids can increase the risk of OUD and/or subsequent death. Consider the following as best practices:

- *Continue Opioid Therapy for Patients in Transition.* Physicians are encouraged to consider providing opioids to patients during transition to avoid dangerous disruptions in care. While the clinician may not have chosen to start opioids for a given chronic pain condition, stopping opioid therapy is different due to the physiological changes

brought on by long-term opioid therapy. Stopping opioid therapy has been shown to increase illicit opioid use, emergency medical care utilization, mental health crises and death from overdose, heart attacks, strokes and suicide. It may be necessary and medically appropriate to continue opioid therapy, particularly if the patient has been doing well on long-term opioids or the patient will have a prolonged wait to see a pain management specialist. Whenever possible, discuss the patient's history with their former clinician, complete baseline assessments of pain and review expectations for opioid prescribing. Assess presence of opioid use disorder and discuss treatment if appropriate. If unable to treat the patient, provide a direct provider to provider hand-off to another clinician to avoid the experience or perception of abandonment.

- *Continue Successful Treatment Protocols for Long-Term Stable Intractable Pain Patients with Multi-System Complications.* Physicians should avoid mandating changes to treatment regimens that are succeeding as changes in medication protocols, once such a patient is stable, are frequently destabilizing and very harmful to these complex, often frail patients. The cardiovascular, endocrine and neurological complications experienced by these patients are challenging to treat and successful protocols may seem unusual. Such patients may have benefited from stimulants, benzodiazepines, and other medications co-prescribed with opioid pain medications to optimally manage their pain **and** multi-system complications. In these cases, the best practice is to keep doing what works. For these patients, the current protocol represents the pinnacle of individualized, patient-centered care. Forced tapering or forced change in regimen may bring about unnecessary suffering, disruption of life, and loss of quality time for patients who have already suffered greatly before finding their successful regimens. Such forced change not only disrupts the lives of these patients during the transition, but may never result in outcomes as good as those produced by the regimen from which the patient is being forced to change.

- *Develop* a *Patient-Centered, Individualized Care Plan.* Develop an individualized plan in collaboration with the patient for continuing opioid therapy, tapering down or off opioid therapy, or transitioning to buprenorphine. Engage the patient and include discussions around social issues and support, mental health services, alternative pain management strategies, and overdose risk. Consider the patient's perceived risks and benefits of opioid therapy. Document the rationale for continuing or modifying a patient's opioid therapy.

- *Use Caution when Tapering Opioid Therapy.* Clinicians should not abruptly discontinue or rapidly taper opioids in patients. All patients, including legacy patients, deserve a slow, balanced, empathetic, good faith taper trial. Those that fail tapering may be suffering from a resumption of higher pain levels and the taper may need to be discontinued. Others can be considered for buprenorphine therapy or evaluated for opioid use disorder. Additional information on tapering strategies is discussed in the section titled "Discontinuing Opioid Therapy".

- *Consider the use of Buprenorphine when Appropriate.* Buprenorphine has been shown to be a safe treatment for pain management and OUD and is FDA approved for both conditions. Buprenorphine reduces craving, withdrawal, and overdose risk, has low potential for misuse and diversion, and increases retention in care. **(NOTE: Buprenorphine is unlikely to be a successful treatment for long-term**

intractable pain patients with multi-system complications.)

Legal Cannabis Use and Opioids

Cannabis was legalized for nonmedical use by adults (over 21) in 2016. As part of the initial patient evaluation/assessment, the patient's personal history of alcohol and drug use is explored. Although some studies have shown that the combination of cannabis and opioids can be therapeutic to some chronic pain patients, carefully consider the use of opioid medications in individuals with a history of illicit drug or cannabinoids use. The risk of overdose and development of an opioid use disorder (OUD) is higher in these cases, and therefore the provider should carefully evaluate the use of opioids to justify that the benefits outweigh the risks. Specific counseling on increased risks for overdose should be provided when opioids are combined with concurrent use of substances with depressant effects.

Cannabis use might also come to the attention of the physician through urine drug testing. This is a legal substance so a positive result should not directly result in dismissal of a patient from care unless the use conflicts with the terms of the pain management agreement. Instead, it may be necessary to consider whether to revise or adjust the treatment plan if the patient's progress is unsatisfactory. Physicians may also wish to consider whether consultation with a specialist in addiction medicine is indicated.

Research on the clinical limitations and benefits of cannabis is ongoing by the Center for Medicinal Cannabis among others. It may be helpful to monitor the progress of their research to assess the benefits and risks associated with cannabis use.

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 should be considered a first line treatment. 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. Therefore, physicians should start with lower initial doses, longer dosing intervals and have closer follow up especially in opioid-naive patients. Physicians should anticipate side effects and attempt to prevent them (i.e., universal treatment of constipation, physical therapy or risk assessment for fall prevention, monitoring for cognitive impairment). Because of higher rates of respiratory depression, consider offering a prescription for naloxone if the patient presents an increased risk of overdose. If the patient has a caregiver, evaluate their ability to properly dispense opioid medications and be aware of the possibility of diversion. Because of the complexity of prescribing opioids in older adults, referral and/or consultation with geriatric specialists or pain specialists can be considered. Older adults who are legacy long-term opioid patients may be able to continue their usual regimen if their condition is stable and they have strong support

from family members or other caregivers.

Pediatric Patients

Children of all ages deserve compassionate and effective pain treatment. Effective pain management in the pediatric population is critical since children and adolescents experience a variety of acute and chronic pain conditions associated with common childhood illnesses and injuries, as well as some painful chronic diseases that typically emerge in childhood such as sickle cell anemia and cystic fibrosis.

The same basic principles of appropriate pain management for adults apply to children and teens, which means that a trial of opioids for short term use has a place in the range of treatment options when non-opioid alternatives, including referral to a pain medicine specialist, has failed or is unlikely to be effective for pain. Given the potential risks of opioid analgesics, a careful and thorough patient assessment and risk stratification should be performed. If opioid therapy is initiated, the law requires that the risks be explained to both the minor patient and the patient's parent or guardian before dispensing or issuing the first prescription. The patient/parent must be advised of, 1) the risks of addiction and overdose associated with the use of opioids, 2) the increased risk of addiction to an opioid if the patient is suffering from both mental and substance abuse disorders, 3) the danger of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant. Note: The risk discussion is not required if the minor patient's treatment is for chronic intractable pain, relative to emergency services or surgery or is considered by the physician to be detrimental to the patient's health and safety or violates the minor's rights regarding confidentiality.

Since 2018, the FDA has required safety labeling for prescription cough and cold medicines containing codeine or hydrocodone to indicate that these products should only be used in adults over 18 years. FDA concluded that the risks of slowed or difficult breathing, misuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18.

It is noted that children/adolescents are at a greater risk than adults of becoming addicted when exposed to drugs. The American Academy of Pediatrics recommends universal screening for adolescent substance use as a routine part of health care. The National Institute on Drug Abuse has launched two online screening tools that providers can use to assess for substance use disorder (SUD) risk among adolescents 12-17 years old.

Pregnant Women

Opioid use in pregnancy has escalated dramatically in recent years, paralleling the epidemic observed in the general population. Obstetric care providers need to be knowledgeable about the medical, social, and legal consequences that can accompany opioid use by pregnant women. A joint committee opinion issued by American Congress of Obstetricians and Gynecologists (ACOG) and the American Society of Addiction Medicine (ASAM) makes the following recommendations:

- **Universal** screening for substance use should be part of comprehensive obstetric

care and should be 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).

- Pregnancy provides an important opportunity to identify and treat women with substance use disorders. Identify patients with substance use disorders using validated screening tools, offer brief interventions (i.e., engage the patient in a short conversation when the patient is showing risky substance use behaviors, provide feedback and advice), and provide a referral to brief therapy or treatment as needed.

- For pregnant patients with an opioid use disorder, opioid agonist pharmacotherapy is the recommended therapy and is preferable to medically supervised withdrawal because withdrawal is associated with high relapse rates, leading to worse outcomes.

- Infants born to women who used opioids during pregnancy should be monitored by a pediatric care provider for neonatal abstinence syndrome, a drug withdrawal syndrome that opioid-exposed neonates may experience shortly after birth.

An interactive online toolkit, the Mother and Baby Substance Exposure Initiative, shares best practices to improve outcomes for substance exposed mothers and newborns.

Patients Covered by Workers Compensation

This population of patients presents its own unique circumstances as medical treatment decisions must be reviewed and approved for medical necessity through utilization review. Utilization review programs use medical treatment guidelines developed by the American College of Occupational and Environmental Medicine (ACOEM) and adopted in regulation by California to determine what is reasonable and necessary medical care for an injured worker. These treatment guidelines also address the use of opioids and treatment for chronic pain. The Medical Treatment Utilization Schedule (MTUS) is available online to healthcare providers treating, evaluating, or performing utilization review in the California workers' system.

Patients with History of Substance Use Disorder

Use of opioids for patients with a history of substance use disorder is challenging because such patients are likely to experience greater risks for opioid use disorder and overdose than persons without these conditions. Physicians should ask patients about their drug and alcohol use using validated screening tools such as the Alcohol Use Disorders Identification Test (AUDIT) or TAPS . In addition to these tools, include other assessments such as discussions with patients, family and caregivers, clinical records, CURES data and toxicology screening.

If the patient's medical history, self-report or scores on screening assessment tools suggest an above-average risk of substance use disorder, physicians should consider the following steps in proceeding with a pain management strategy:

- Carefully consider whether benefits of opioids outweigh increased risks.
- Discuss increased risks for opioid use disorder and overdose with patient.
- Provide specific counseling on increased risks for overdose when opioids are combined with other drugs or alcohol.
- Prescribe naloxone and provide education to one or more persons designated by the patient in its use.
- Increase frequency of monitoring using CURES data and drug testing as appropriate to assess for concurrent substance use placing a patient at higher risk for opioid use disorder and overdose.
- If misuse of opioid analgesics is suspected or confirmed, initiate a non-confrontational in-person meeting, use a non-judgmental approach to asking questions, and present options for referral, opioid taper/discontinuation or switching to non-opioid treatments. Avoid "abandoning" the patient or abruptly stopping opioid prescriptions.

Because pain management in patients with a history of substance use disorder can be complex, physicians should consider consulting a specialist in addiction medicine. If the patient has a current history of substance use disorder, communicate with patient's substance use disorder treatment provider if opioids are prescribed.

Patients with Psychiatric Conditions

Psychological distress frequently interferes with improvement of pain and function in patients with chronic pain. Use validated instruments to support assessment for anxiety, post-traumatic stress disorder, and/or depression might help improve overall pain treatment outcomes. Examples include the Generalized Anxiety Disorder (GAD)-7, the Patient Health Questionnaire (PHQ)-9 and PROMIS Depression and Anxiety assessment measures among others. In addition, patients with anxiety disorders and other mental health conditions are more likely to receive benzodiazepines, which can exacerbate opioid-induced respiratory depression and increase risk for overdose. Consult with behavioral health specialists when needed.

Patients Prescribed Benzodiazepines

Physicians should use caution when prescribing opioids and benzodiazepines concurrently. There may be circumstances when it might be appropriate to prescribe opioids to a patient who is also prescribed benzodiazepines (e.g., 1) severe acute pain in a patient taking long-term stable low-dose benzodiazepine therapy or 2) a patient with intractable pain and multi-system complications on a successful long-term treatment protocol that includes a benzodiazepine), however, physicians should use caution when prescribing these drugs concurrently. Physicians should also consider whether the benefits outweigh risks of concurrent use of opioids with other central nervous system depressants (e.g., muscle relaxants, non-benzodiazepine sedative hypnotics, potentially sedating anticonvulsant medications such as gabapentin and pregabalin).

Patients taking benzodiazepines and opioids are at an increased risk for respiratory

depression and overdose. 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. CDC recommends that a prescription for naloxone be provided when opioid use ≥ 50 MMEs/day. 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. Education on opioid overdose prevention and the use of naloxone must also be provided to the patient and individual(s) designated by patient. For additional information, see Prescribe to Prevent for prescribing and dispensing naloxone (Narcan) rescue kits.

If the risks are determined to outweigh the benefits of continuing the opioid and benzodiazepine therapy and a decision is made to taper one or more medications, develop an individualized tapering strategy based on the clinical situation of the patient. An example of an opioid tapering strategy is available in the Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics.
Examples of benzodiazepine tapers and tips for managing withdrawal are available through the Department of Veteran's Affairs.

Physicians should communicate with mental health professionals managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure and coordinate care.

Telehealth

Telehealth is seen as a tool in medical practice, not a separate form of medicine. The law states that prescribing without an appropriate prior examination and a medical indication is unprofessional conduct. However, an appropriate exam does not require a synchronous interaction between the patient and physician and can be conducted via telehealth. As always, the physician must comply with the appropriate standard of care.

As discussed previously, a thorough patient assessment is critical when considering long term use of opioids for chronic pain. While it is preferable to conduct a face-to-face evaluation of the patient's condition as part of this assessment, there may be circumstances that make this challenging. Physicians are expected to use their best clinical judgement and patient-centered decision making to determine how best to ensure that a thorough assessment is performed before prescribing opioids and to adequately monitor patient progress for the duration of treatment.

As of March 31, 2020, an exception was made for clinicians to prescribe buprenorphine to new and existing patients for OUD via telehealth as long as an adequate evaluation can be conducted by telephone. A DATA 2000 waiver can be obtained from the Substance Abuse and Mental Health Services Administration (SAMHSA) to allow practitioners to forego the training and counseling requirements if treating 30 patients or less with buprenorphine for OUD.