

SB264
March 24th 2021
Opponent
Nick Reinecker

Senate Ways and Means

Chair: Senator Rick Billinger

Until cannabis is de-scheduled, I do not support any government growth bill that has to do with addiction. There is too much gray state language in this bill that could be used discriminately on the low-hanging fruit and green vegetable matter that is cannabis. We have seen this type of operation in the Kansas Expanded Lottery Act dealing with "other addictions" that are not about problem gambling. When we think about the simultaneous promotion and abatement apparatus of state gambling, alcohol and tobacco, both in campaign finance and legislative lifting, Kansas does not need more government intervention in this area unless, for this bill's purpose, it is specifically and exclusively used, as opioid litigation implies, for Opioid Use Disorder. It is important to understand there are only certain behaviors like problem gambling or substances that are an actual diagnosable Substance Use Disorder/Gambling Disorder. When we think of addiction in this narrow scope there are unintended consequences. For those who espouse certain faiths the concept that most easily relates is idolatry. If one believes in the Christian God then there should be no other god before God. I submit that anything can be an idol/addiction. Ice cream, politics, sex, fraternities, screens; phone, tv, etc. The problem I have with a lot of these public health strategies is that it doesn't focus on the more harmful legal (alcohol, caffeine and tobacco) substances nor even the more harmful illegal substances like methamphetamine or heroin, but a plant that has a premium feed profile, industrial applications and therapeutic uses that are being stifled in both research and access, regardless of private prisons or using government-intervention cycling substance users as revenue generators.

Thank you

Nick Reinecker

<https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf>

http://www.kslegislature.org/li_2020/b2019_20/committees/ctte_h_ins_1/documents/testimony/20200210_35.pdf

The Joint Commission's Pain Standards: Origins and Evolution

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In 2001, as part of a national effort to address the widespread problem of underassessment and undertreatment of pain, The Joint Commission (formerly The Joint Commission on the Accreditation of Healthcare Organizations or JCAHO) introduced standards for organizations to improve their care for patients with pain.¹ For over a decade, experts had called for better assessment and more aggressive treatment, including the use of opioids.² Many doctors were afraid to prescribe opioids despite a widely cited article suggesting that addiction was rare when opioids were used for short-term pain.³ Education, guidelines, and advocacy had not changed practice, and leaders called for stronger methods to address the problem.⁴⁻⁷ The standards were based on the available evidence and the strong consensus opinions of experts in the field.

After initial accolades and small studies showing the benefits of following the standards, reports began to emerge about adverse events from overly aggressive treatment, particularly respiratory depression after receiving opioids. A report from The Institute for Safe Medication Practices (ISMP) asked, “Has safety been compromised in our noble efforts to alleviate pain?”⁸ In response to these unintended consequences, the standards and related materials were quickly changed to address some of the problems that had arisen. But lingering criticisms of the standards continue to this day, often based on misperceptions of what the current standards actually say.

This article reviews the history of The Joint Commission standards, the changes that were made over time to try to maintain the positive effects they had on pain assessment and management while mitigating the unintended consequences, and recent efforts to update the standards and add new standards to address today’s opioid epidemic in the United States. A recent commentary⁹ discussed how the lessons learned from this analysis may inform our country’s current efforts to address the prescription opioid crisis.¹⁰ Our goal is to ensure that the pendulum of medical practice does not swing back toward the poor pain control of the past, but instead comes to rest in a position that balances effective pain treatment with safe opioid prescribing for individual patients and the general population.

The Clarion Call for a Different Approach to Improve Assessment and Treatment of Pain

In 1990, Dr. Mitchell Max, the President of the American Pain Society, wrote an editorial in *Annals of Internal Medicine* decrying the lack of improvement in pain assessment and treatment over the previous 20 years.² Education, advocacy, and guidelines from the U.S. Agency for Health Care Policy and Research, the American Pain Society, and the World Health Organization had not worked.⁴⁻⁷ This failure was attributed to patients not telling their doctors and nurses about their pain, nurses not being able to adjust doses, and physician reluctance to use opioids. Pain was often invisible: “Unlike ‘vital signs,’ pain isn’t displayed in a prominent place on the chart or at the bedside or nursing station.” Physicians were “rarely held accountable” for inadequate pain control, and they had not implemented systems to address the problem. “Pain relief has been nobody’s job.”

It was time for a different approach. Dr. Max recommended:

- Make pain “visible.”
- Give practitioners “bedside” tools for change to guide physicians and nurses to initiate and modify analgesic treatments.
- Assure patients a place in the “communications loop.”
- Increase clinician accountability by developing “quality assurance guidelines,” improving care systems, and assessing patient satisfaction.
- Facilitate innovation and exchange of ideas.
- Work with narcotics control authorities to encourage therapeutic opiate use.

Dr. Max emphasized the conventional wisdom of the day that “therapeutic use of opiate analgesics rarely results in addiction,” although this was based on only a single publication that lacked detail about how the study was done.³ He lauded the Wisconsin Controlled Substances Board’s Cancer Pain Initiative that led to a tenfold increase in morphine prescribing over a 12-year period.^{11,12}

Turning the Call into Action

The following year, the American Pain Society released quality assurance standards for relief of acute pain and cancer pain.¹³ The standards followed Dr. Max’s previous recommendations, including: 1) chart and display pain and relief, 2) a simple, valid measure of pain intensity should be selected by each unit, and 3) each clinical unit should identify values for pain intensity rating and pain relief rating that will elicit a review of the current pain therapy. This latter recommendation is likely to have led to the use of pain treatment algorithms that later proved to be highly problematic. Progress was slow, but in 1999 California’s legislature passed Assembly Bill 791, which added to the Health and Safety Code (HSC) that “Every health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The pain assessment shall be noted in the patient’s chart in a manner consistent with other vital signs.”¹⁴ Finally, on October 31, 2000, the 106th U.S. Congress passed H.R. 3244; title VI, Sec. 1603 established the “Decade of Pain Control and Research.”¹⁵

The Joint Commission’s First Pain Standards

In 1997, the Robert Wood Johnson Foundation funded The Joint Commission to develop pain standards in collaboration with the University of Wisconsin-Madison School of Medicine and experts from around the country. Three years later, Dr. Dennis O’Leary, President of the Joint Commission on Accreditation of Healthcare Organizations (now The Joint Commission), announced standards for health care organizations to improve pain management.¹ Dr. O’Leary emphasized the need for the standards due to the confusion over who was responsible for pain control, a general lack of knowledge about pain management, and misconceptions about drug tolerance and addiction. Responsibility was being placed on health care organizations: “The pain management paradigm is about to shift.” Dr. O’Leary emphasized the need for organizations to do systematic assessments and use quantitative measures of pain (e.g., place pain on a 10-point scale),¹ which was consistent with positions of The American Pain Society,⁶ reports by the Institute of Medicine,¹⁶ and the U.S. Veterans Health Administration’s “Pain: The Fifth Vital Sign.”¹⁷

In addition to the standards themselves, The Joint Commission compiled a manual that brought all of the standards together into one place.¹⁸ They also provided “Examples of Implementation” to describe how other organizations had successfully demonstrated compliance with a standard, stressing that these were “NOT standards, nor are they required ways to meet a standard.”

Early Accolades and Successes

The Joint Commission standards were hailed by pain management specialists and called “a rare and important opportunity for widespread and sustainable improvement in how pain is managed in the United States.”¹⁹ Frasco and colleagues implemented an initiative to address the standards in their perioperative care unit. A numeric pain scale became “mandatory” in the post anesthesia care unit (PACU), and an “acceptable” pain score was required for discharge from the PACU.²⁰ The average consumption of opiates per patient increased from 40.4 mg (morphine equivalents) in 2000 to 46.6 mg in 2002, with the greatest increase in the PACU (6.5 mg to 10.5 mg). There was no increase in length of stay, naloxone use, or nausea and vomiting. In other settings, non-pharmacologic therapies were explored in response to the standards. Diette and colleagues reported that “distraction therapy” with nature sights and sounds during flexible bronchoscopy improved patient ratings of pain control.²¹ The standards’ recommendation to use patients’ self-reported pain using numerical scales was supported by a study that found emergency department nurses significantly underestimated patients’ pain compared to patients’ self-report (4.2 vs. 7.7 on a ten-point scale).²² However, no large national studies were conducted to examine whether the standards improved pain assessment or control.

Negative Reactions and Unintended Consequences

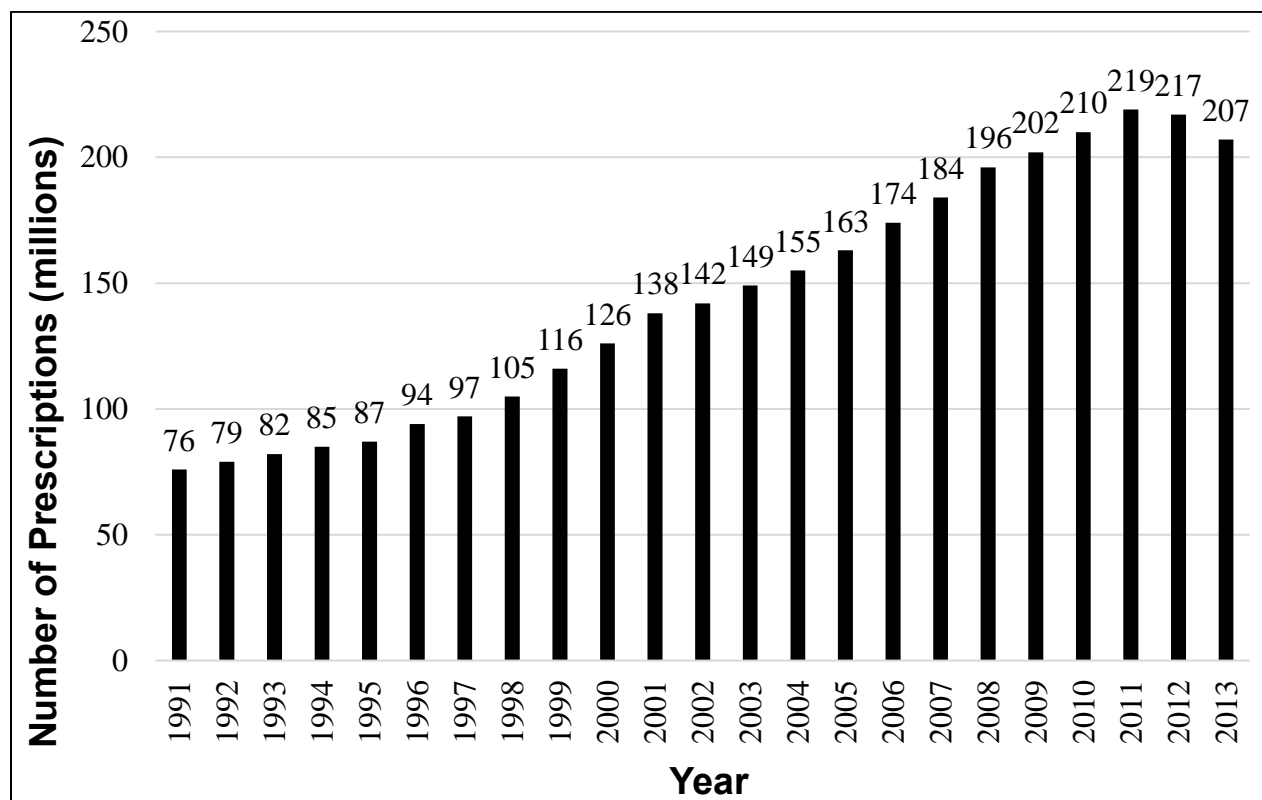
Although the standards targeted health care organizations, some physicians saw the standards as an intrusion into their practice. A 2002 report from the American Medical Association’s Council on Scientific Affairs found these concerns were due to lack of clarity of some Examples of Implementation.²³ Concerns were raised that requiring all patients to be screened for the presence of pain and raising pain treatment to a “patients’ rights” issue could lead to overreliance on opioids.²⁴ Such concerns were criticized by pain experts as “opioidphobic.”²⁵ Nurses raised concerns about statements on the Joint Commission website that implied organizations could no longer use “PRN” range analgesic orders without specific implementation protocols.²⁶ Neither concern reflected an accurate interpretation of the standards, and The Joint Commission clarified that the concern was not the use of PRN orders per se, but rather PRN orders that were written ambiguously; fixed algorithms for adjusting pain medications were not needed. Use of the “fifth vital sign” phrase also proved to be problematic; rather than seeing the phrase as an analogy to draw attention to the need for improved assessment (“Make pain visible”), some organizations interpreted this to mean that pain needed to be assessed every time vital signs were taken.

There were also signs that some clinicians had become overzealous in treating pain. A 2003 survey was conducted using a random sample of 250 adults who had undergone surgical procedures in the U.S.;²⁷ 80% had post-operative pain, 86% of these rated their pain moderate to “extreme,” and post-operative pain was the most common concern for 59% of respondents. However, 90% of patients in the study said they were satisfied with their pain medications. Despite this extremely high satisfaction rate, the authors concluded that “many patients continue to experience intense pain after surgery” and “additional efforts are required to improve patients’ postoperative pain experience.” Pain had become the enemy that needed to be eradicated. Many organizations implemented treatment policies and algorithms based on patients’ responses to numerical pain scales.²⁸ One study reported that the incidence of opioid oversedation increased from 11.0 to 24.5 per 100,000 inpatient days after the hospital implemented a numerical pain treatment algorithm.²⁹ Soon after this, the Institute for Safe Medication Practices (ISMP) linked overaggressive pain management to an alarming increase in oversedation and fatal respiratory depression events.³⁰

Changes in Prescription Opioid Use

Immediately after the release of the standards in 2001, some raised concerns that the standards could lead to inappropriate use of opioids.²⁴ Total opioid prescriptions had been steadily increasing in the U.S. for at least a decade before the standards were released (see Figure 1 below).³¹ Between 1991 and 1997, the number of prescriptions increased from 76 million to 97 million. This was likely due to advocacy work by pain experts, as described above. From 1997 to 2013, the rate of increase appears to have been somewhat more rapid. Some of this acceleration in the rate of increase in opioid prescribing may have been due to the 1995 approval of the new sustained-release opioid OxyContin.³² The Food and Drug Administration (FDA) approved labeling saying that iatrogenic addiction was “very rare” and that the delayed absorption of OxyContin reduced the abuse liability of the drug.³² These same claims were used in marketing campaigns to physicians and in more than 40 national pain-management and speaker training conferences for which all expenses were paid.³² The FDA required removal of these unsubstantiated claims from OxyContin’s labeling in 2001. However, the concept that iatrogenic addiction was rare and that long-acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later.^{33,34} Because of the steady rise in opioid prescriptions in the decade preceding release of The Joint Commission standards and the other forces encouraging opioid prescribing in the years before the release of the standards, it is difficult to draw conclusions about whether the standards or educational materials related to the standards had an independent effect on the upward trend.

Figure 1. Opioid Prescriptions Dispensed by U.S. Retail Pharmacies, 1991-2013.



Changes to the Standards and Examples of Implementation

In response to safety concerns and the misinterpretation of the Examples of Implementation, The Joint Commission made multiple changes to the standards and Examples of

Implementation over the next few years. The 2001 Example of Implementation that said “Pain is considered a ‘fifth’ vital sign in the hospital’s care of patients” was changed in 2002 to say “Pain used to be considered the fifth vital sign.” By 2004, this phrase no longer appeared in the Accreditation Standards manual, although the phrase remained in some Joint Commission educational materials for several years after that. All Examples of Implementation were completely eliminated a few years later.

The standard that pain be assessed in all patients also remained controversial. Arguments centered around two issues: 1) for some patients, the question seemed inappropriate because of the nature of their main medical issue, and 2) no similar standard existed requiring the universal assessment of other symptoms. This requirement was finally eliminated in 2009, except for patients in behavioral health care who were thought to be less able to bring up the fact that they were in pain and, therefore, required a more aggressive approach. Finally, in response to criticisms that the standards encouraged opioid use, The Joint Commission added the following note to its standards in 2011: “Both pharmacologic and nonpharmacologic strategies have a role in the management of pain. The following examples are not exhaustive, but strategies may include the following: Nonpharmacologic strategies: physical modalities (for example, acupuncture therapy, chiropractic therapy, osteopathic manipulative treatment, massage therapy, and physical therapy), relaxation therapy, and cognitive behavioral therapy; Pharmacologic strategies: nonopioid, opioid, and adjuvant analgesics.”

Current Efforts

In early 2016, The Joint Commission began a project to both revise its pain assessment and management standards and to develop standards related to safe and judicious prescribing of opioids. Three main areas were identified on this topic: 1) assessment and management of acute pain, 2) assessment and management of chronic pain, and 3) recognition, management, and/or referral of patients addicted to opioids. The Joint Commission decided to concentrate first on acute pain in the hospital setting.

After an initial literature review, The Joint Commission constituted a Technical Advisory Panel for potential conflicts of interest.¹⁸ All nominees were evaluated for potential conflicts of interest. In late 2016, new standards were drafted based on a literature review, input from the Technical Advisory Panel, and learning visits to organizations that had implemented innovative strategies to improve pain assessment and management. The draft standards were released in January 2017 and made available for public comments through February 2017.¹⁸ The draft standards recommend that pain assessment: include identification of psychosocial risk factors that may affect self-reporting of pain; involve patients to develop their treatment plan and set realistic expectations and measurable goals; focus reassessment on how pain impairs physical function (e.g., ability to turn over in bed after surgery); monitor opioid prescribing patterns; and promote access to nonpharmacologic pain treatment modalities. Changes to promote safe opioid use during and after hospitalization and to prevent diversion include: identify high risk patients; have equipment available to monitor high risk patients; facilitate clinician access to prescription drug monitoring program (PDMP) databases and encourage PDMP use prior to prescribing opioids; and educate patients and families regarding the safe use, storage, and disposal of opioids. Finally, The Joint Commission recommends that hospitals make efforts to identify patients addicted to opioids and to facilitate referral for treatment by informing clinicians about local addiction treatment programs.

The Joint Commission anticipates publication of the final standards in July 2017 for implementation January 1, 2018. These also will be made publicly available on our website.¹⁸ The Joint Commission also plans to provide educational tools and resources to help

organizations meet the new standards. As scientific evidence and policy evolves, The Joint Commission stands ready to make additional changes as needed to help health care organizations improve pain control while simultaneously minimizing misuse of opioids and harm to patients and the broader population.

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