

SPECIAL REPORT

MIEC Claims Alert

Number 47
March 2017

Opioid Pain Medications: Regulatory Update

In This Issue:

- We explore the recent history of opioids for the treatment of chronic pain, and the changing regulatory landscape
- We review the common elements of state medical board guidelines pertaining to opioid management
- We explore the recent CDC Guideline for Prescribing Opioids for Chronic Pain and examine how it differs from state prescribing guidelines
- We discuss state Prescription Drug Monitoring Programs (PDMPs) and how they should be used to evaluate patients’ risk profiles and compliance in the setting of chronic opioid treatment
- We examine the potential effects of reduced prescribing of opioids, including physician reaction and access to care, and efforts to improve overall pain management strategies

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Special Report Claims Alert

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A (Not So) Brief History of an Epidemic:

In the January 2013 issue of The Exchange, we used the analogy of a swinging pendulum to describe the shifting policy regarding pain management and the use of opioid pain medications. Back in 1996, in response to a perceived undertreatment of pain, the American Pain Society promoted the concept of “Pain as the 5th Vital Sign” to urge physicians to recognize, evaluate, and effectively treat pain both in the outpatient and acute care settings. With the advent of “safe” extended-release opioid formulations such as OxyContin[®], which came on market in

1996, physicians began to feel more comfortable prescribing opioids for the treatment of chronic pain in the outpatient setting.¹

By 2003, state medical boards had updated their guidelines to require the appropriate evaluation and treatment of both acute and chronic pain. Indeed, physicians were disciplined, as well as sued, for allegedly failing to reduce patients’ pain.

Meanwhile the amounts of prescribed opioids in the U.S. soared. Per the U.S. Centers for Disease Control and Prevention (CDC), between 1992 and 2015

¹ Pain as 5th Vital Sign — American Pain Society, http://american-painsociety.org/uploads/education/section_2.pdf.

total opioid prescriptions increased from 112 million to 249 million. Along with increasing prescriptions, the number of adverse events rose dramatically. From 1999 to 2014, over 165,000 deaths occurred from overdoses related to prescription opioids. The rate of fatal overdoses of prescription opioids has quadrupled since 1999, and there were over 14,000 deaths related to prescription opioids in 2014 alone. By 2014 it was estimated almost 2 million individuals abused or were dependent on opioids.²

In 2013 we reported that the national policy towards opioids was shifting, partly in response to a November 2011 declaration by the (CDC) that prescription drug abuse had become a “national epidemic.”³

In Spring 2013, the Federation of State Medical Boards (FSMB) released its revised Model Policy for the Use of Controlled Substances for the Treatment of Pain, which in turn led to the updating of state medical board guidelines. The updated guideline, while still recommending that physicians recognize and treat legitimate pain, added several recommendations to minimize the potential for abuse and diversion of nar-

cotic pain medications, and to recognize and prevent the use of them outside legitimate medical purposes.

Meanwhile, authorities were significantly stepping up their discipline, and even criminal prosecution, of physicians for overprescribing opioid pain medications. Beginning in 2013, the DEA Diversion Office, which initially had pursued large-scale pharmaceutical distributors, refocused their efforts on physicians, pharmacists, and smaller organizations.⁴

As we begin 2017, it is now safe to say that the pendulum has fully swung. The increased prosecution and discipline of physicians has continued. In February 2016, a Southern California physician was convicted of second-degree murder and sentenced to 30 years to life in prison for the deaths of three patients from opioid overdose. This was the first time a physician had been convicted of murder in relation to prescribing pain medications.⁵

Here are some other pivotal events in 2016 that marked the changing national attitude towards opioid pain medications and the management of chronic pain:

March 15, 2016 — The CDC released its Guideline for Prescribing Opioids for Chronic Pain, which endorses ever tighter restrictions on the use of opioid pain medications outside of active cancer treatment, palliative care, and end-of-life care.

March 18, 2016 — The Department of Health and Human Services (HHS) released its National Pain Strategy, intended to recognize that access to safe and effective treatment of pain is a public health priority, and an essential part of addressing the opioid epidemic along with efforts to curb inappropriate opioid prescribing and use practices. The HHS strategy is intended to be used along with safer prescribing practices, such as those recommended by the CDC.

March 22, 2016 — The Federal Drug Administration (FDA) announced required “black box” warnings on all immediate-release opioids regarding the serious risks of misuse, abuse, addiction, overdose and death associated with those medications.⁶

June 2016 — The American Medical Association recommended dropping the concept of “pain as the 5th vital sign” and passed several other resolutions to reduce the

2 CDC statistics, <http://www.cdc.gov/drugoverdose/data/index.html>.

3 CDC press release November 1, 2011 — Prescription Painkiller Overdoses at Epidemic Levels, https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

4 Bernstein, Larry and Higham, Scott, “Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control.” *Washington Post*, October 22, 2016.

5 Gerber, Marisa, “Doctor convicted of murder for patients’ drug overdoses gets 30 years to life in prison.” *Los Angeles Times*, February 6, 2016.

6 FDA news release March 22, 2016 — FDA announces enhanced warnings for immediate-release opioid pain medications related to risk of misuse, abuse, addiction, overdose and death, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm>.

prescription of opioid pain medications.⁷

August 2016 — The U.S. Surgeon General sent a letter to every physician in the nation urging them to reduce opioid addiction by educating themselves on safe and effective pain management, including following the CDC guideline; screening patients for opioid use disorder and providing evidence-based addiction treatment; and treating addiction as a chronic illness. Additionally, physicians were provided with a pocket guide on safe prescribing, and they were asked to take an online pledge to “turn the tide” on the opioid crisis.⁸

Meanwhile, a series of high-profile deaths from opioid overdose helped to publicize the national war on opioid abuse, including the April 2016 death of an iconic musician which shocked the country and brought the scale of the opioid abuse epidemic into focus.

Since that time, it has been difficult to read the news without encountering a story about the dangers of opioid abuse and the perceived need for large-scale reform in pain management. Recently, the national discussion has spread from the epidemic of overdose-related injuries and

deaths, to the lifelong affliction of opioid addiction.

In this issue of *The Exchange*, we explore the recent updates to pain management guidelines, including the current state medical board guidelines, the updated CDC guideline, and provide MIEC’s recommendations for best practices to improve patient care and reduce liability when prescribing opioids for chronic pain management.

State Medical Board Guidelines

Virtually all states maintain written prescribing policies that not only serve as guidelines for safe management of opioid pain medications, but also provide the legal basis under which state medical boards investigate and discipline physicians for their prescribing practices.

Recently, there have been instances of physicians also being held criminally liable under federal drug laws, for failing to meet their state’s prescribing standards. The Controlled Substances Act (CSA) (21 USC 841(a)) generally does not apply to health care providers, unless it can be demonstrated that the provider’s conduct fell “outside the usual course of professional practice.” Penalties for violation of the CSA can include seizure of personal assets, loss of medical license, and prison

sentences ranging from 20 years to life in cases of serious bodily injury (including hospitalization, or even serious withdrawal syndrome) or death.

In 2016 two Idaho physicians were convicted under the CSA, after the prosecution applied the Idaho Board of Medicine guidelines to demonstrate that their management of opioids failed to meet those guidelines, and thus fell outside the usual course of professional practice for physicians. Both physicians are awaiting criminal sentencing.

The Federation of State Medical Boards (FSMB) issued its updated Model Policy for opioid management in 2013, and this resulted in individual states updating their own policies and guidelines.

The FSMB Model Policy was developed to address several perceived shortcomings in the management of pain, and to make it clear that the following shortcomings would constitute a departure from accepted best clinical practices:

- Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a patient
- Inadequate monitoring during the use of potentially abusable medications

⁷ Anson, Pat, “AMA Drops Pain as Vital Sign,” Pain News Network, June 16, 2016, <https://www.painnewsnetwork.org/stories/2016/6/16/ama-drops-pain-as-vital-sign>.

⁸ Surgeon General Letter to Physicians, Turn the TideRx, August 2016, <http://turnthetiderx.org>.

- Inadequate attention to patient education and informed consent
- Unjustified dose escalation without adequate attention to risks or alternative treatments
- Excessive reliance on opioids, particularly high-dose opioids, for chronic pain management
- Not making use of available tools for risk mitigation

The FSMB Model Policy includes the following recommendations, many of which have been incorporated into state board guidelines:

Understanding pain:

- Understand the relevant pharmacologic and clinical issues, risks and benefits for individual patients

Patient evaluation and risk stratification:

- Conduct a good faith exam, review of systems, lab studies
- Evaluate effects of pain on activities of daily living
- Review prior records to verify patient's history
- Conduct a social and vocational assessment, talk with family and evaluate support systems
- Evaluate personal/family history of drug/alcohol abuse, consultation with addiction specialist or

enrollment in rehab program if appropriate

- Use a validated screening tool (Screener and Opioid Assessment for Patients with Pain, Opioid Risk Tool) to determine level of risk
- Perform a mental health screening/assessment
- Confirm verbal history by reviewing records
- Check state prescription monitoring database

Development of treatment plan and goals:

- Reasonable improvements in pain and functioning
- Improving pain-associated symptoms such as sleep disturbances, depression
- Avoiding excessive use of medications

Informed consent and treatment agreement:

- Discuss anticipated benefits and risks including tolerance, dependence, addiction, and overdose
- Discuss the limited evidence of the benefit of long-term opioids
- Explain the office policy on prescribing, refills, replacement of lost/stolen medications
- Require patients to sign a treatment agreement ("pain management contract") outlining physician and

patient responsibilities for ongoing treatment

Initiating an opioid trial:

- Consider safer alternatives before starting opioid therapy
- Initiate a trial course of opioids for 90 days or less
- For opioid naïve patients, begin with the lowest possible dose while titrating to effect
- Begin with short-acting opioids before considering long-acting/extended-release opioids, if indicated

Ongoing monitoring and adapting the treatment plan:

- Regularly review patients' progress while on opioids
- See patients more frequently when initiating or increasing opioids
- Obtain information from collateral sources such as family members or state PDMP
- Follow the "5 A's" to determine success of the treatment plan:
 - Analgesia- reduction in level of pain
 - Activity- increased level of function
 - Adverse effects- any significant side effects or adverse events

-Aberrant behavior-evidence of substance abuse or intoxication

- Affect- patient's mood

Periodic drug testing:

- Screen for appropriate levels of the prescribed opioid to confirm compliance
- Confirm the absence of nonprescribed medications or illicit drugs
- Urine testing is preferred

Consultation and referral:

- Seek consultation or referral to pain management, mental health, or addiction specialist as needed
- Know the treatment options for opioid addiction

Discontinuing opioid therapy:

- Discontinue treatment for resolution of the underlying condition, intolerable side effects, inadequate analgesic effect, failure to improve quality of life, deteriorating function, or aberrant use
- Initiate a safe tapering regimen if the patient is physically dependent on medications
- Continue opioid treatment only if the patient has demonstrated a benefit, including functional improvement

Medical records:

- Maintain complete records including medical history, physical exam, lab

results, results of opioid risk assessment, detailed medication records, patient instructions, informed consent discussion, signed consent form, treatment agreement, consultations or evaluations by specialists

Compliance with controlled substance laws and regulations:

- Maintain a current DEA registration and state licensure

The full FSMB model policy can be found here:

http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf

For information on opioid prescribing guidelines in the states in which MIEC insures, see **Table 1**.

Table 1

Alaska:

The Alaska State Medical Board substantially updated its Policies and Procedures for prescribing controlled substances in November 2015. In addition to the practice guidelines established in 1997, the document added language from the FSMB regarding departure from best clinical practices.

In August 2016, the Board added the CDC guideline to the available tools for risk mitigation which prescribers must use under the Policies and Procedures.

https://www.commerce.alaska.gov/web/portals/5/pub/med_guide_prescribing_controlled_substances.pdf

Table 1, *continued***California:**

The Medical Board of California (MBC) adopted all of the recommendations set forth by the FSMB when it revised its Guidelines for Prescribing Controlled Substances for Pain in November 2014.

The MBC recommends that physicians “proceed cautiously” once patients reach a daily dose of 80 MME/day or greater, and that referral to an appropriate specialist be considered before further increasing the dose.

http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf

Hawaii:

The Hawaii Board of Medical Examiners (BME) has not updated its guidelines since the updated FSMB model policy. Pursuant to the Uniform Controlled Substances Act, the BME established its pain management guidelines in 2006:

http://files.hawaii.gov/dcca/pvl/news-releases/medical_announcements/pain_management_guidelines.pdf

There are two bills pending in the HI state legislature which, if passed during the 2017 session, would significantly amend the existing Uniform Controlled Substances Act. SB798 would require any prescriber of a narcotic medication to establish a written pain management agreement with any existing patient prescribed a narcotic for chronic pain for 3 months or more, or with any new patient being prescribed a narcotic at the initial visit. The pain management agreement would have several required components, including informed consent, random pill counts, and urine drug testing at least three times per year.

SB1229 would establish a drug take-back program and minimum CME requirements; require narcotic prescribers to register with and obtain patient information from the PDMP before prescribing narcotics; require the use of a pain management agreement; and create immunity for those who provide an opioid antagonist in the setting of overdose.⁹

Idaho:

The Idaho Board of Medicine updated its Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain in September 2013. The policy essentially adopted the FSMB model policy in its entirety.

<https://bom.idaho.gov/BOMPortal/BOM/PDF%20FORMS/ModelPolicyUseofOpioidAnalgesicsinTreatmentofChronicPain.pdf>

⁹ Hawaii SB798, SB1229, http://www.capitol.hawaii.gov/measure_indiv.aspx?billtype=SB&billnumber=1229
http://www.capitol.hawaii.gov/measure_indiv.aspx?billtype=SB&billnumber=798.

CDC Guideline for Prescribing Opioids for Chronic Pain

The CDC guideline, released in March 2016, focuses on reducing the overall prescription of opioids, particularly for chronic pain. The guideline consists of 12 individual recommendations, but they essentially rely on three principles:

“Use non-opioid therapies”- Non-opioid treatment is preferred for chronic pain outside of cancer, palliative care, and end-of-life care.

“Start low and go slow”- When choosing opioids, providers should prescribe the lowest possible effective dose to avoid opioid use disorder and overdose.

“Follow up”- Providers should always exercise caution and closely monitor patients when prescribing opioids.

The specific recommendations are as follows:

Determining when to initiate or continue opioids for chronic pain:

The dosage recommendations for exercising caution are lower than older opioid prescribing guidelines. Higher doses of opioids are associated with higher risk of overdose and death; even relatively low doses of 20-50 morphine milligram equiva-

lents (MME) per day increase risk.

- 1) Nonpharmacologic therapies (such as physical therapy, cognitive behavioral therapy, weight loss, or certain interventional procedures) and non-opioid pharmacologic therapies (such as anti-inflammatories) are preferred for chronic pain. Do not use opioids routinely for chronic pain; consider opioid therapy only if the expected benefits for both pain and function are expected to outweigh risks to the patient. When opioids are used, combine them with nonpharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.
- 2) Establish treatment goals with all patients, including realistic goals for pain and function, and consider how to discontinue therapy if risks outweigh benefits.
- 3) Discuss risks and realistic benefits of opioid therapy with patients, as well as patient and clinician responsibilities for managing therapy before starting, and periodically during, opioid therapy.

Opioid selection, dosage, duration, follow-up and discontinuation:

The guideline provides more specific recommendations compared to previous guidelines on monitoring and discontinuing opioids when risks and harms outweigh benefits.

- 4) At the beginning of opioid therapy for chronic pain, prescribe immediate-release opioids instead of extended-release or long-acting opioids, such as methadone, transdermal fentanyl, and extended-release versions of opioids such as oxycodone, oxymorphone, hydrocodone, and morphine.
- 5) Prescribe the lowest effective dosage and use caution when prescribing opioids at any dosage. Carefully reassess risk and benefits when increasing dosage to 50 morphine milligram equivalents (MME) or more per day and avoid increasing dosage to 90 MME or more per day.
- 6) Limit the duration of opioid prescriptions for acute pain. Typically, three days' worth of medication is sufficient, and more than seven days' worth is rarely needed.

- 7) Evaluate benefits and harms with patients as early as one week and no more than four weeks after starting therapy for chronic pain or escalating doses, and again after no more than three months. Taper dosages or discontinue opioids if necessary.

Assessing risk and addressing harms of opioid use:

Previous guidelines focused safety precautions on “high risk patients.” However, the CDC argues that opioids pose risk to all patients, and currently available tools cannot rule out risk for abuse or other serious harm. The CDC guideline provides recommendations on providing safer care for all patients including the use of recent technological advances, such as state prescription drug monitoring programs.

- 8) Incorporate into the opioid therapy management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for overdose are present, such as a history of overdose or substance abuse, concurrent benzodiazepines, or opioid dosages over 50 MME/day. Before starting and periodically during opioid therapy,

evaluate risk factors for addiction or overdose.

- 9) Use your state prescription drug monitoring program (PDMP) data to see whether a patient is getting opioids from other providers at dosages, or in combinations with other drugs, that create a high risk of overdose. Review PDMP data every 3 months during treatment.
- 10) Order urine drug testing before starting opioid therapy and consider repeating at least annually during treatment.
- 11) Avoid prescribing opioid pain medication and benzodiazepines at the same time whenever possible.
- 12) Offer or arrange evidence-based treatment for patients with opioid use disorder.

Further information regarding the CDC guideline can be found here:

<http://www.cdc.gov/drugoverdose/index.html>

Importantly, the CDC guideline is not prescriptive; that is, it provides voluntary recommendations for managing opioid therapy but does not impose any requirements on providers. However, there are several reasons physicians

should follow the guideline in clinical practice.

First, the CDC guideline has been publicized to the extent that lay jurors, most of whom have likely heard of the guideline, may not fully appreciate the differences between those voluntary recommendations, requirements under state law, and the community standard of care. Furthermore, the extent of recent media coverage on the opioid epidemic has been such that it is becoming increasingly difficult to find jurors who are impartial on the subject. Current clinical guidelines do not define the standard of care and may not have been in place at the time care was rendered. However, in litigation, plaintiff attorneys are increasingly attempting to present updated guidelines as evidence of standard of care or “safety rules,” so that they may demonstrate a departure from recommendations intended to protect the safety of patients.

Secondly, since the release of the CDC guideline, some states have proposed legislation to codify various individual CDC recommendations into legal requirements, similar to how state guidelines have been used.

Thirdly, health insurers may begin using the CDC recommendations as a basis for treatment authorization.

MIEC recommends that prescribers become familiar with both state medical board guidelines and the CDC guideline, and that the most stringent recommendations be followed when the state and federal guidelines are inconsistent. At a minimum, as described above, prescribers must follow applicable state law and prescribing standards to avoid licensure action and/or criminal prosecution.

MIEC recommends that physicians learn and always remain in compliance with prescribing guidelines set by their state medical board. The CDC guideline should be followed if feasible, and any deviation from the recommendations in any guideline should be accompanied by thorough documentation of the reasons why.

Prescription Drug Monitoring Programs

Current prescribing guidelines encourage the reliance on state Prescription Drug Monitoring Programs (PDMPs) to check patients' compliance with prescribing regimens, and to ensure that patients are not obtaining pain medications from multiple providers. Some states are also beginning to enact laws requiring physicians to register with the PDMP and/or obtain reports on patients prior to prescribing controlled substances.

State PDMPs store prescription information for dispensed Schedule II, III, and IV controlled substances. The databases generally contain the following information: patient name, patient date of birth, patient address, prescriber name, prescriber DEA number, pharmacy name, pharmacy license number, date prescription was

dispensed, prescription number, drug name, drug quantity and strength, and number of refills remaining.

Importantly, PDMPs allow prescribing providers who are registered with the system to request a Patient Activity Report (PAR) for a patient, which will reflect all controlled substances prescribed to that patient including those from other providers. Patients can request copies of their PAR directly from the PDMP.

Importantly, state PDMP information is also used by licensing and law enforcement authorities to assist in the investigation and/or prosecution of physicians based on their individual prescribing histories.

Currently, all states with exception of Missouri and the District of Columbia have active PDMPs. For PDMP information for the states in which MIEC insures, see **Table 2.**

Table 2

Alaska:

Alaska requires both pharmacies and dispensing practitioners to report all controlled substances dispensed during the previous month, other than those administered to a patient at a health care facility. Reports of the previous month's substances must be made by the fifth day of each month.

SB74, which was recently passed by the Alaska legislature and will take effect on July 17, 2017, requires all physicians to register with the PDMP and to review PDMP information before dispensing, prescribing, or administering a Schedule II

Table 2, *continued*

or III controlled substance. Exceptions include medications provided in an inpatient setting; at the scene of an emergency, or in an ambulance or ER; immediately before, during, or within the first 48 hours after surgery or a medical procedure; in a hospice or nursing home with an in-house pharmacy; or in a non-refillable quantity lasting no more than 3 days.¹⁰

Alaska physicians can learn more about Alaska's PDMP (AKPDMP) at:

<https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy/PrescriptionDrugMonitoringProgram.aspx>

California:

In 1999 the Controlled Substance Utilization Review and Evaluation System (CURES) replaced the Triplicate Prescription Program in California as the state's PDMP. The program, operated by the Department of Justice, added a searchable client-based resource in 2009. CURES 2.0 was released in July 2015, with a streamlined registration process and several system upgrades.

CA Health and Safety Code Section 11165.1 requires health care practitioners authorized to prescribe, order, administer, furnish, or dispense scheduled controlled substances must submit a CURES 2.0 registration application to the Department of Justice before July 1, 2016, or upon receipt of a DEA registration. Thus, all prescribing physicians in California should now be registered with CURES 2.0. Existing registrants with CURES 1.0 are automatically registered, but will be asked to change their password after the initial login.

To register with CURES, complete the online registration form at the following address:

<https://cures.doj.ca.gov/registration/confirmEmailPnDRegistration.xhtml>

Senate Bill 482, recently signed into law by Governor Brown on September 27, 2016, requires California doctors and nurses to check the CURES database for signs of abuse when initially prescribing opioid pain medications, as well as steroids, sleep aids and psychiatric medications. The law, which is not yet in effect, will require providers to recheck the database every four months for if the medication is continued.

California physicians can learn more about CURES at: <https://oag.ca.gov/cures>

¹⁰ Alaska SB74, http://www.akleg.gov/basis/get_bill.asp?session=29&bill=sb++74.

Table 2, *continued*

Hawaii:

Hawaii has no requirements for minimal use of their PDMP, although physician participation is highly encouraged. As we noted, pending legislation in Hawaii would require providers to register for and use the PDMP before prescribing controlled substances to patients.

Hawaii physicians can learn more about Hawaii's PDMP (RxSentry) at:

<https://hipdmp-ph.hidinc.com/hilogappl/bdhipdmpqlog/pmqhome.html>

Idaho

Effective July 1, 2014, every prescriber must annually register with the ID Board of Pharmacy to obtain online access to the state PDMP. Idaho does not require physicians to check the PDMP before prescribing controlled substances.

Idaho physicians can learn more about Idaho's PDMP (AWARxE) at:

<https://bop.idaho.gov/pmp/>

Physician Reaction and Access to Pain Management

The recent “war” on opioids, and the regulatory approach to addressing the challenges of pain management, have been met with mixed reactions from physicians.

The CDC guideline, in particular, has been met with some criticism. The CDC guideline was based, in part, on a systematic review of research studies which concluded that evidence is limited as to the long-term benefits of opioid therapy for chronic pain, but that evidence did show a dose-dependent risk of serious harm with chronic opioid therapy. Critics have pointed

out that the research evidence for pain management in general is very limited; thus, the absence of evidence on the therapeutic value of opioids is not due to a lack of benefit, but rather to a lack of research.

Another controversial issue with the CDC guideline is the inclusion of opioid dosage thresholds (50 and 90 MME/day), as well as duration thresholds for acute pain (3 and 7 days). Dosage thresholds require providers to calculate a patient's total daily dosage and then convert that into MME, which is a process that could be prone to error. Additionally, there

is concern that providers will have difficulty establishing the “lowest effective dosage” in certain patients while effectively treating pain, particularly given the paucity of clinical data available on the effectiveness of opioid pain medications.¹¹

Anecdotally, MIEC has encountered many physicians in the primary care setting who are no longer providing any opioid pain medications, because of both the tightening guidelines around management and a perceived shortage of specialty Pain

¹¹ Duensing JD, Katie, Goldstein MSW, Amy et al., “Opioid Dosage & Morphine Equivalency: Implications for Meeting the Standard of Care when Comparing CDC Recommendations to State Policies,” State Pain Policy Advocacy Network, September 2016, <http://www.aapainmanage.org/wp-content/uploads/Opioid-Dosage-and-Morphine-Equivalency2.pdf>.

Management services preventing them from being able to freely refer patients that require higher levels of care. There are concerns that the shifting policies towards reduced prescribing of opioids will result in reduced access to care for those chronic pain patients who legitimately require opioid pain medications to adequately manage their pain, and some are worried that this will lead to a higher incidence of heroin abuse.

American Academy of Pain Medicine:

While cautiously supporting the CDC guideline, shortly following its release the American Academy of Pain Medicine (AAPM) issued a statement stressing the need to address the treatment of chronic pain, in addition to opioid abuse, as a public health challenge.

In its March 16, 2016 statement, the AAPM referenced opioids as “an important option – as part of a comprehensive multidisciplinary approach – that must remain available to physicians and appropriately selected patients,” and stated that it shared concerns that “the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”

Shortly thereafter, the AAPM issued a further statement applauding the release of the HHS National Pain Strategy, which provides a framework for improving the overall management of pain. The AAPM noted that, as the opioid epidemic likely recedes due to reduction strategies such as the CDC guidelines, stakeholders will look towards the HHS recommendations for guidance on developing system-level approaches to improve the assessment, treatment, and prevention of pain.¹²

HHS National Pain Strategy:

The HHS National Pain Strategy (NPS) recommends improving pain care in 6 key areas: population research; prevention and care; disparities; service delivery and payment; professional education and training; and public education and communication.

More specifically, the NPS calls for:

- Developing methods and metrics to monitor and improve the prevention and management of pain
- Supporting the development of a system of patient-centered integrated pain management practices

based on a biopsychosocial model of care, enabling providers and patients to access the full spectrum of pain treatment options

- Reducing barriers to pain management and improving quality of pain care for underserved populations
- Increasing public awareness of pain, increasing patient knowledge of treatment options and risks, and helping to develop a better-informed health care workforce with regards to pain management

The NPS also provides opportunities for reducing the need for and over-reliance on prescription opioid medications, including:

- Improving provider education on pain management practices and team-based pain management involving multiple treatment modalities
- Improving patient self-management strategies and access to quality, multidisciplinary care that does not depend solely on prescription medications
- Encouraging the evaluation of risks and benefits of current pain treatment regimens
- Providing patients with educational tools to encour-

12 American Academy of Pain Medicine statements March 16, 2016, and March 18, 2016, <http://www.painmed.org/files/aapm-statement-cdc-guideline-for-prescribing-opioids-for-chronic-pain.pdf>, <http://www.painmed.org/files/aapm-statement-national-pain-strategy.pdf>.

age safer use of prescription opioids

- Conducting research to identify how best to provide the appropriate pain treatments to individual patients based on their unique medical conditions and preferences

The HHS has also developed an opioid initiative, which focuses on informing opioid prescribing practices, increasing the use of naloxone (Narcan) for overdoses, and expanding access to treatment of opioid use disorder.

More information on the HHS National Pain Strategy can be found here:

<https://iprcc.nih.gov/docs/DraftHH-NSNationalPainStrategy.pdf>

Recommendations from MIEC Patient Safety & Risk Management:

- Be familiar with your state medical board guidelines for using controlled substances to treat pain, and always adhere to state guidelines to avoid civil liability, licensure action, and/or criminal liability
- Adhere to the CDC Guideline for Prescribing Opioids for Chronic Pain whenever possible, and carefully document your rationale if providing treatment that is not consistent with the recommendations.

- Try non-opioid therapies first for chronic pain, or demonstrate failure of non-opioid therapies before prescribing chronic opioids.
- Conduct and document a full risk assessment before prescribing opioids.
- Focus on and document a functional assessment as well as pain symptoms and physical exam results.
- Develop progress notes specifically for chronic pain patients, which include measures of effectiveness of treatment.
- Have patients sign a pain management agreement and require them to adhere to the agreement.
- Conduct routine urine testing and other standard screening for opioid use disorder.
- Beware the “90-day cliff” and carefully re-evaluate patients before continuing opioids past 3 months.
- Develop policies to re-evaluate patients when increasing opioids past 50 MME/day, and do not exceed 90 MME/day without documented reasons.
- Don’t assume that patients on stable dosages of 50 MME/day or less are being appropriately managed;

re-evaluate for efficacy of current treatment and lower dosage if appropriate.

- Register for your state PDMP and routinely obtain patient reports prior to, and regularly during, opioid prescription.
- Familiarize yourself with “black box” warnings for all controlled substances you prescribe.
- Know your state’s CME requirements, if any, pertaining to education in pain management.

How to reach MIEC:

Phone:

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Honolulu: 808/531-5224

Boise: 208/344-7903

Alaska: 907/868-2805

Outside of area: 800/227-4527

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Oakland: 510/654-4634

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