OPIOID ANALGESICS IN CALIFORNIA:
Relieving Pain, Preventing Misuse, Finding Balance

June 2013
Table of Contents

Executive Summary .....................................................................................................................................2
Introduction ................................................................................................................................................3
Opioid Issues in California............................................................................................................................8
Finding Solutions ......................................................................................................................................10
CMA Recommendations ............................................................................................................................12
Summary .................................................................................................................................................15
References...............................................................................................................................................16
Executive Summary

Like the nation as a whole, California is faced with a serious health care dilemma: how to use opioid medications safely and effectively to relieve pain, while simultaneously reducing the risk of prescription medication misuse, addiction and overdose. This paper puts forth key considerations and recommendations on how to achieve a balance. All parties involved in this complex issue can, and must, work together to advance pain care while minimizing risks to patients and society. The California Medical Association (CMA) believes that opioids have a legitimate role in medical practice and can be safe and effective when prescribed responsibly.

Recommendations include:

- **Education:** Encourage the education of prescribers, policymakers and the public
- **Tools:** Establish and fund a range of tools, including California’s prescription drug monitoring program and drug take-back and substance abuse treatment programs, to improve patient and public safety
- **Data:** Obtain additional data on opioid misuse specific to California
- **Evaluation:** Maintain the physician role in evaluating appropriate pain management and use of opioids
Introduction

The pendulum of opinion about the safety, efficacy and proper use of opioid pain medications has swung markedly in recent years. Concerns about the documented under-treatment of pain in the 1990s were so serious that California enacted laws to promote and protect pain management-related activities. Two decades later, growing concerns about prescription medication misuse and opioid misuse in particular, has brought nationwide calls for instituting prescriber and dispenser limitations, as well as for an expansion of law enforcement investigations of physicians.

Although some proposed legislative and regulatory actions could potentially address current inadequacies (such as properly funding a prescription drug monitoring program), other actions being considered could erode the progress in pain management practices that have been made over the course of decades. Opioids remain an important part of the pain management toolbox. They are not the only tool, nor necessarily the best tool, for every patient, but for some, opioids can improve function, ease suffering and improve overall quality of life.

Although physicians play an important role in implementing solutions to reduce prescription opioid misuse and overdose, they are just one of many stakeholders involved with this issue. No single group can solve this problem, and no single law, policy change or initiative will suffice. Effective solutions require a sustained, cooperative effort on the part of all stakeholders, including physicians, patients, law enforcement and regulatory agencies, insurers, and the pharmaceutical industry. The goal is to bring the swinging pendulum of opinion to rest at a stable, healthy point of balance between minimizing misuse of prescription opioids and ensuring access for their legitimate use.

A Brief History of Opioid Use, Misuse and Regulation

Opioids are among the world’s oldest known drugs. They have been used both medicinally and recreationally for over 5,000 years. Historical use of opioids to relieve pain, however, was crude and uninformed by an understanding of either pain or the opioids themselves. With scientific advances, more pure and powerful opioid formulations were developed and more effective, accurate and safe use became possible. The addictive potential of opioids has also been long established and non-clinical use was criminalized in 1914. In 1970, the U.S. enacted the Controlled Substances Act (CSA), which acknowledged and formalized both the medicinal benefit and the abuse potential of opioids. The CSA continues to guide federal drug policy.

In the 1990s, evidence for a high prevalence of untreated or inappropriately treated pain led to efforts to raise awareness about pain and to encourage clinicians to expand the use of opioids beyond the realms of severe acute pain or intractable end-of-life pain, for which these medications were traditionally reserved. The expanded use of opioids in the treatment of pain was supported by numerous professional practice guidelines. Collective efforts to improve pain treatment, along with pharmaceutical industry marketing initiatives, fueled a quadrupling of opioid analgesic sales between 1999 and 2010. Society was attempting to address the significant under-treatment of pain and opioids were widely regarded as a legitimate option. At the time, many leading clinicians viewed opioid analgesic therapy as a relatively low-risk endeavor that was well-tolerated and appropriate for a wide range of patients.

Evidence and knowledge have since accumulated that opioid medications carry more risk and require a greater level of monitoring for safe use than was previously appreciated. With the increased use of prescription of opioids, there has been a corresponding rise in the misuse of these medications (chart below). According to national surveys conducted by the Substance Abuse and Mental Health Services Administration between 1998 and 2008, the national rate of reported opioid misuse

---

i: "Misuse" is used in this document to designate intentional or unintentional inappropriate use, including abuse, non-medical misuse, medical misuse and diversion. More specific terms are used where appropriate.

ii: An older term, “opiates,” referred specifically to preparations derived from opium itself. The word “opioids” is preferred today and refers to all drugs either made from opium directly or synthesized to have opium-like effects.
increased 400%. Other research reported that emergency-room visits related to non-medical use of opioids rose 111% between 2004 and 2008.

While reliable California-specific data on opioid misuse is limited, there is some data on general trends for drug misuse in general. In California, combined data from 2010 and 2011 suggest that the rate of past year non-medical use of prescription pain relievers (not just opioids) among those aged 12 or older was 4.7%, slightly higher than the national rate of 4.6%. Drug overdose deaths (including illegal drugs) in California in 2008 were 10.4 deaths per 100,000 people, which is below the U.S. average of 12.3 overdose deaths per 100,000 people.

In response to rising concerns, in 2011 the White House Office of National Drug Control Policy, in collaboration with other branches of the federal government, introduced the “Action Plan to Address National Prescription Drug Abuse Epidemic.” The U.S. Food and Drug Administration (FDA) and U.S. Drug Enforcement Agency (DEA) have also recently proposed and revised regulations related to opioid prescribing.

Rates of opioid pain reliever (OPR) overdose death, OPR treatment admissions, and kilograms of OPR sold — United States, 1999–2010

* Age-adjusted rates per 100,000 population for OPR deaths, crude rates per 10,000 population for OPR abuse treatment admissions, and crude rates per 10,000 population for kilograms of OPR sold.

The private sector has taken action as well. For example, abuse-deterrent and tamper-resistant opioid formulations have been developed by pharmaceutical companies. Although abuse-deterrent opioid formulations do not prevent users from simply consuming too much of a medication, they may make it more difficult for drug abusers to get the high they seek, and therefore discourage some forms of misuse.11

Recent increased media coverage has driven some California legislators to respond with proposals to change the regulatory system. Topics under discussion include changes to the Medical Board of California (MBC) investigation process, limits on opioid prescribing within the Workers’ Compensation system, the role of coroner reporting in identifying inappropriate prescribing, and funding and improving California’s prescription drug monitoring program (PDMP).

Progress in making effective change requires all stakeholders to work together to define and implement rational approaches for the safe and effective use of opioids. An important part of that discussion is developing a shared understanding of what pain is, how opioids are used as one tool to manage pain, and how existing regulatory controls impact prescribing practices.

Foundational Knowledge About Pain

An appreciation for the proper role of opioids in pain relief requires understanding some fundamental aspects of pain itself. The internationally adopted definition of pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.”12 It has also been said that “Pain is what the patient says it is.”13 The latter definition alludes to the subjective nature of pain and is a reminder that, with the rare exception of patients with intent to deceive, a patient’s own self-report is the most reliable indicator of pain and pain severity.14 The subjectivity of pain, particularly when the cause is not visible, can lead to the stigmatization of those with pain and those who treat pain.

Pain can be classified by how long it lasts, although this is not the most clinically useful approach. Acute pain is defined as relatively short-term pain arising from obvious tissue injury, and usually fades with healing.15 Chronic pain or persistent pain, in contrast, has been defined as pain that lasts longer than would be anticipated for the usual course of a given condition (other definitions use arbitrary cut-off times of 3 months or 6 months of unrelieved pain). Unfortunately, the terms “acute” and “chronic” provide no information about the biomedical nature of the pain itself, which is often of critical importance.

A more useful nomenclature classifies pain on the basis of its physiological and pathological nature. Nociceptive pain is caused by the activation of nociceptors—specialized nerve cells that respond when stimulated by heat, cold, injury, disease, inflammation or chemical irritation. Nociceptive pain is generally (but not always) short-lived, and is associated with the presence of the underlying medical condition. This type of pain serves as a beneficial warning system of tissue damage. Almost everyone has felt this pain—it is deemed credible and can generally be treated effectively.

Neuropathic pain, on the other hand, occurs either when there is an injury to the nervous system or when nociceptive pain is not adequately treated. Neuropathic pain, as the name implies, is caused by abnormal excitation of nerves in the absence of active tissue damage. Neuropathic pain can be difficult to diagnose and to manage because effective treatment options are limited. Neuropathic pain can be considered a neuro-biological disease that serves no beneficial function. As a disease, neuropathic pain is a highly complex process that involves genetics, physiologic, pathologic, biochemical and molecular changes in the body, and eventually becomes a generator of pain without external stimuli.16

Differentiating between nociceptive and neuropathic pain is critical because the two types of pain respond differently to pain treatments. Specifically, neuropathic pain typically responds poorly to both opioid analgesics and non-steroidal anti-inflammatory (NSAID) agents.17 Importantly, many patients present in the clinic with “compound” pain that has both nociceptive and neuropathic components. That makes evaluation and management even more challenging.

Pain can be a symptom, a disease (an anatomical or physiological abnormality), or a combination of both. Pain can also be an illness, which refers to the impact of a disease on a person. Persistent neuropathic pain is a chronic illness and similar
to other chronic illnesses, such as chronic heart disease or cancer, there can be significant co-morbidities having biological, psychological and social ramifications that must be addressed.

Pain Management
The primary goals of effective pain management are: decreased pain and suffering; improved functioning (work force and societal); and decreased reliance on the health care system. To achieve these goals, a variety of pain management tools are available to clinicians. Options include cognitive and behavioral approaches, rehabilitative approaches, surgery, complementary and alternative therapies, and medications including, but not limited to, opioids.

Not all of these options are necessary or appropriate for every patient, but clinical guidelines suggest that all of these options should at least be considered every time a health care provider treats a patient in pain. These options can be used alone or in combinations to achieve the best possible pain control and functional gains. Which options are used with a given patient depend on careful consideration of many factors such as the type of pain, the duration and severity of pain, patient preferences, co-occurring disease states or illnesses (including drug addiction), patient life expectancy, cost, and the availability of the treatment option.

Opioids: Efficacy and Proper Uses
Opioids are effective pain relievers because, at a molecular level, they resemble compounds, such as endorphins, which are produced naturally in the human central nervous system. Opioids bind to receptors in the brain and body, resulting in both therapeutic effects (such as pain relief) and undesirable side effects (such as constipation and respiratory depression). Opioids, as a class, comprise many specific agents available in a wide range of formulations. Short-acting, orally-administered opioids typically have rapid onset of action (10-60 min.) and relatively short duration of action (2-4 hours). They are used most often for short-duration nociceptive pain, or breakthrough pain that occurs against a background of persistent controlled pain.

Extended-release/long-acting opioids have a relatively slow onset of action (typically between 30 and 90 min.) and a relatively long duration of action (4 to 72 hours). Such agents are typically used for patients with persistent pain.

It is important to emphasize that patients may respond quite differently to any specific opioid or any given combination of medications. One size does not fit all when it comes to pain management, and treatment is best optimized on an individual basis. This requires a close relationship between the prescribing physician and the patient and generally takes time to accomplish.

Opioid Safety and Risk Management
All drugs, including opioids, can produce anticipated side effects or potentially more serious adverse events. Other forms of treatment, such as surgery, involve their own set of risks. Physicians are taught to weigh the risk/benefit ratio every time they consider a mode of treatment. Perceived benefits should always outweigh perceived risks.

Potential side effects of opioids include respiratory depression, sedation, confusion, below-normal levels of testosterone or estrogen, nausea, vomiting, constipation, itching, and urinary retention. With the exception of constipation, many of these side effects tend to diminish with time, and constipation can usually be effectively treated with other therapeutic agents. Uncomfortable or unpleasant side effects (again with the exception of constipation) may be reduced by switching to another opioid or route of administration, or in some cases may also be alleviated with adjunctive medications.

Like other controlled substances such as sedatives, stimulants, anti-anxiety medications and some muscle relaxants, opioids may cause or contribute to addiction in susceptible individuals. Unfortunately, the risk of addiction among patients with no history of substance abuse that have been prescribed opioid pain medications is unknown, but at the very least mirrors the risk in the general population, estimated to be 7-10%. Most clinicians recognize that in the population of patients who suffer chronic pain and are treated with opiate analgesic therapy, the incidence and prevalence of substance abuse disorder is higher.
than the general population, being between 10-25%. This reality emphasizes the need to assess patient risk and provide proper monitoring and screening when using opioid analgesic therapy.iii

Opioids should be used cautiously in patients with conditions that may be complicated by known adverse effects, including patients with chronic obstructive pulmonary disease (COPD), congestive heart failure, sleep apnea, current or past alcohol or substance misuse, mental illness, advanced age, or patients with a history of kidney or liver dysfunction. In addition, opioids should not be combined with other respiratory depressants, such as alcohol or sedative-hypnotics (benzodiazepines or barbiturates).

Particularly in cases of persistent pain, a decision to use opioids should be based on a clearly understood knowledge of the potential risks and benefits and be arrived at jointly by both physician and patient. An evaluation should always occur prior to prescribing, though this may be challenging due to the subjective and multidimensional nature of pain. Obtaining a complete patient history, review of past medical records, physical examination, psycho-social evaluation, and assessment of potential for substance abuse are all parts of a complete evaluation.

A written treatment plan for any patient prescribed an opioid analgesic may be helpful to both patients and physicians. Such plans can improve patient/physician communication, clarify patient expectations and responsibilities, establish a transparent and enduring record of a physician’s treatment rationale, and set clear guidelines for treatment monitoring.

Treatment goals should be developed mutually between patient and physician. A patient’s reported degree of pain is just one of many variables to consider in framing functional goals, which must be realistic, meaningful to the patient and verifiable. Careful monitoring and ongoing evaluation, which may include drug screening and prescription monitoring, are essential.

**Regulatory Controls**

Opioids, like other controlled substances, are regulated by both federal and California laws, which authorize licensed physicians to prescribe them for legitimate medical purposes, in accordance with the current standard of medical care. A physician must obtain a DEA registration after obtaining a state license in order to prescribe controlled substances.

The U.S. Controlled Substances Act places drugs into five “schedules” based on whether they are determined to have a currently accepted medical use in the United States and on their perceived abuse potential and/or likelihood of causing dependence. Schedule I substances are judged to have a high potential for abuse and no currently accepted medical use in the United States, and include heroin and LSD. Schedule II substances are viewed as having a high potential for abuse or which may lead to psychological or physical dependence, and yet also have an accepted medical use in the United States. Most opioid pain medications are Schedule II drugs. Schedule III substances are considered to have a lower potential for abuse than substances in Schedules I or II. Examples of Schedule III opioids include combination products containing less than 15 milligrams of hydrocodone, an opioid, per dosage unit (i.e., Vicodin). Drugs in Schedules IV and V are considered to have lower potentials for abuse than other schedules. Where a drug is scheduled impacts prescribing practice. For example, prescriptions for Schedule II drugs cannot be automatically refilled and cannot be filled via a phone call from a physician to a pharmacy, except in limited and defined situations.

The MBC has authority to discipline physicians who fail to meet minimum standards of care or who violate California’s Medical Practice Act (MPA). Enforcement is a critical aspect of the MBC’s mandate to protect consumers. The MPA requires the MBC to take action against any licensee who is charged with unprofessional conduct. The MBC will refer cases warranting legal action to the California Attorney General.

---

iii: While most opioids are used for pain management, patients who have an established opioid use disorder may require chronic opioid replacement therapy (CORT) to treat their disorder. Depending on the specific opioids used in CORT, services are either provided in a specially designated, credentialed and licensed facility, or in a practice setting by a qualifying physician who has received special registration to provide CORT. In the latter situation, an evaluation by an expert in addiction medicine working in conjunction with a pain medicine specialist may be very helpful both in monitoring and providing advice to the clinician.
Other boards that oversee health licensees who can prescribe and dispense medication have the same consumer protection role. The California Board of Pharmacy is particularly relevant to discussions of prescription opioid misuse. Pharmacists have a corresponding responsibility to ensure that prescriptions are filled only for a legitimate medical purpose.

California law specifically gives patients a right to certain kinds of pain medication, including opioids, where medically indicated. A physician who is unable or unwilling to provide this treatment option has an obligation to tell the patient that they may seek treatment from another physician. Legal cases, including those in California, show that physicians who provide inadequate pain treatment have been vulnerable to tort liability and disciplinary action by medical boards.20,21

The Department of Workers’ Compensation (DWC) is another aspect of California’s regulatory picture, with its own set of regulations and mechanisms for enforcement, including aspects that relate to opioid use. People who are injured on the job present unique circumstances. Generally, injured workers are sent to a participating facility or practitioner for treatment, and treatment may include opioid analgesics. DWC policy can shape the range of treatment options available, and it employs law enforcement personnel to assure that patients and prescribers are not abusing the system. The California Medical Treatment Utilization Schedule (MTUS) guides DWC treatment options and includes a robust discussion on chronic pain, including opiate analgesic therapy.v

**Opioid Issues in California**

Given the growing concerns and attention to prescription opioid misuse, California policymakers raised a number of questions during the first half of 2013.

**What tools are needed to monitor prescription drug use and misuse?**

Physicians may use a variety of tools or resources to monitor prescription drug use. A particularly important tool is a prescription drug monitoring program (PDMP), which allows pre-registered prescribers and dispensers to access controlled substance history information for patients. California’s PDMP is called the Controlled Substance Utilization Review and Evaluation System (CURES). Under the oversight of the Attorney General, the California Department of Justice (DOJ) manages CURES.

The public health mission of CURES is to prevent pharmaceuticals from falling into the wrong hands while promoting legitimate medical practice and quality patient care. If prescribers and dispensaries have access to accurate and timely controlled substance history information at the point of care, it can help them identify and assist patients who may be abusing controlled substances. Use of CURES can also help guide prescribing decisions, and, thus, cut down on prescription drug abuse.

However, funding cuts at DOJ have created significant system and staffing limitations. The DOJ reports that the current system cannot accommodate all 212,000 licensed California prescribers and pharmacists as registered users. It can be difficult for a user to access information in an efficient manner, and DOJ acknowledges that the computer system is slow and can freeze when large reports are requested.22 Inadequate staffing levels at DOJ negatively impact the time it takes to register and approve a user, and severely limit the ability of CURES staff to respond to user questions and problems related to registering for or accessing the system. There is currently a lag between when a prescription is filled and when it appears in the system, which can be as long as several weeks depending on when the dispensing information is filed and if there are any errors detected in the data that require correction. Until the system is redesigned, current limitations will continue to impact clinical use.

Further, in addition to the infrastructure costs, the time and effort required to use a PDMP must be considered, and this can be significant given CURES’ current limitations. While CURES is clearly a valuable tool, mandatory checking of CURES every time any

---

iv: See the Pain Patient’s Bill of Rights and the Intractable Pain Treatment Act, in which the California Legislature acknowledged that prescription medications, including controlled substances, can play a critical role in the treatment of pain, and that prescribing controlled substances, in and of itself, is an insufficient basis to determine if a physician has violated the standard of care in the treatment of pain management patients.

v: (CCR section 9792.20-9792.26)
controlled substance is prescribed is not a wise use of resources, particularly at a time when California is striving to deliver health care in a more efficient manner. For example, mandatory checking is impractical in many settings, such as a busy emergency room in which opioids are prescribed for acute pain related to trauma. Similarly, post-operative settings and assisting patients with cancer do not fit the “doctor shopping” for drugs scenario. In these situations and others, a requirement to check every prescription every time is unduly burdensome, and takes away from the time a physician can spend with the patient.

Can regulatory changes help us identify inappropriate prescribing?

There is no simple formula for determining appropriate and inappropriate prescribing. The term “overprescribing” is used widely, but is vague and arbitrary. There is no set dose threshold that defines “overprescribing.” This is particularly true in the case of opioids because the development of drug tolerance can lead to long-term dose increases that may appropriately and legitimately be required for adequate pain control. Further, the term “overprescribing” also fails to acknowledge inappropriate prescribing in the other direction: when a physician fails to prescribe or prescribes too little, which can also result in harm.

Looking at a physician’s prescribing patterns alone is inadequate, as a physician’s specialty will impact the scope of prescribing for controlled substances. Oncologists, for example, who often treat patients in extreme cancer pain, are likely to prescribe far more controlled substances than pediatricians. In order to understand and investigate potentially inappropriate prescribing, physicians with relevant knowledge must be involved in evaluation of allegations.

Another area of concern relates to the determination of cause of death. Current law requires coroners to report to the appropriate licensing board when gross negligence or incompetence is suspected, but there has been a call for additional mandated reporting from coroners when a death may involve prescription drugs. There are many technical concerns with this proposal, however.

First, the presence of a prescription drug, or opioid specifically, does not equal a cause of death, let alone negligence. Many patients who suffer from chronic pain and are taking a pain medication also have life-threatening diseases, such as heart disease and high blood pressure, which can cause death on their own. There are also significant scientific and procedural limitations to toxicity testing. Tolerance for a drug can vary from person to person, and tolerance in an individual builds over time. This can lead to levels of the drug in a body that might be considered toxic in a forensic examination, but may have been medically appropriate.

A difficulty is that most physicians use urine drug screening to monitor patient compliance with prescriptions. Most coroners, on the other hand, use blood samples to quantify levels of medications in a body. There are no current standards for the measurement of blood levels in the management of persistent pain with opioid analgesic therapy. This can lead to a false attribution of cause of death as “multiple acute combined drug toxicity” because drugs are present post-mortem, without any pre-mortem data on blood levels. More forensic and clinical research must be conducted before scientifically determining that an “overdose” related to a specific substance is the cause of a person’s death.

Should California limit the availability of opioid analgesics?

Discussion on establishing limits on the use of opioids in the management of injured workers is an issue currently under intense evaluation by the DWC. As a result of the recently passed Senate Bill 863, the Medical Evidence Evaluation Advisory Committee (MEEAC), working under the DWC, is updating the MTUS with a supplement specifically addressing chronic opioid analgesic therapy and its role in the management of injured workers. Which treatment options are available within the Workers' Compensation system is a key consideration.

In pain management, a variety of tools are available to clinicians. Options include cognitive and behavioral approaches, rehabilitative approaches, surgery, complementary and alternative therapies, and medications including, but not limited to, opioids. In the circumstance of the injured worker, the physician is faced with limited treatment options if non-pharmacologic
options have been delayed, modified or denied. An unintended consequence of efforts to control cost and utilization of non-pharmacologic services in pain management is an increased reliance on chronic opioid analgesic therapy, and therefore an increase in opioid prescribing. A system in which there is a full set of treatment options that can be accessed by a patient in a timely manner presents the best opportunity for the management of workers’ injuries.

For those injured workers for which chronic opioid analgesic therapy is appropriate, placing limits on prescribing is not consistent with appropriate medical treatment. Some patients may develop tolerance to a medication that can lead to increased long-term dosages that may be appropriately and legitimately required for adequate pain control. One size does not fit all when it comes to pain management, and treatment is best optimized on an individual basis.

**Finding Solutions**

CMA believes that effective answers to the broad questions discussed above require consideration of three fundamental principles, detailed below.

**Physicians, patients, law enforcement, and the general public need accurate information about appropriate opioid use and better data on the factors involved in misuse.**

Public discussions of opioid use and misuse can be muddied by the presentation of misleading and inaccurate information. For example, data about drug overdose deaths in general may be cited as deaths from “opioids” without acknowledgement that the data include deaths from illicit opioids, such as heroin, or that alcohol was involved. In addition, data about concurrent use of drugs by people who die of overdose may be missing or inaccurately presented. This is critical to understand because about half of deaths involving prescription painkillers involve other drugs, including alcohol or illegal drugs.\(^{24,25}\) Statistics may include suicides or those who are terminally ill. As previously described, there are significant scientific and procedural limitations to determining accurately if a death was due to a prescription drug overdose, and this must be considered when evaluating statistics related to cause of death.

In addition, key terms are often misused, including “addiction,” “dependence” and “tolerance” (see below).\(^ {18}\) Patients treated with prolonged opioid therapy almost certainly develop physical dependence (as is the case with many other drugs) and may result in tolerance, but these are not the same as addiction.

---

**Key Terms Defined**

To help clarify and standardize understanding, the American Society of Addiction Medicine (ASAM), the American Academy of Pain Medicine (AAPM), and the American Pain Society (APS) have recommended the following definitions:

**Addiction:** a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

**Physical Dependence:** a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

**Tolerance:** a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time.
No single effort, law, policy change, or initiative will solve the complex problem related to the number of prescription drug-related deaths and injuries, including those involving opioids.

Physicians are not by any means the only players in the issue of prescription drug abuse. Patient expectation is influenced by pharmaceutical company marketing, for example. Dentists, veterinarians, and others also prescribe controlled substances. Pharmacists have corresponding responsibility to ensure proper dispensing. Insurance policies impact what types of treatment will be covered. All of the licensing boards must provide consumer protection. Opioids can be obtained for non-medical use at many points in the manufacturing, distribution, prescribing and disposal systems. For these reasons, and more, there is a need for a comprehensive approach to address the many facets of the problem.

In addition, once patients have obtained medication through legitimate means, they have a responsibility to use the drugs in the manner prescribed by the physician, which includes not mixing opioids with alcohol or illicit drugs. They also have a responsibility to secure and dispose of any unused drugs in a manner that keeps medication from falling into the wrong hands. According to the 2011 National Survey on Drug Use and Health, for persons aged 12 or older in 2010-2011 who used pain relievers non-medically in the past year, 70.8 percent obtained the pain relievers they most recently used from a friend or relative for free, bought them from a friend or relative, or stole them from a friend or relative. This suggests the importance of non-medical strategies, such as providing drug take-back opportunities and education on how to safely store and dispose of unneeded opioids.

In 2011, 70.8% of people who abused prescription pain relievers got them through friends or relatives. - 2011 National Survey on Drug Use and Health

Effective solutions to the problem of prescription drug abuse will therefore require sustained effort on the part of all prescribers (not just physicians), the public, law enforcement and regulatory agencies, insurers, and the pharmaceutical industry.

The disadvantages posed by the use of opioid medications must be weighed against the disadvantages of untreated or inappropriately treated pain.

Of concern to the medical community is the potential in the current societal backlash against opioid pain medications for losing the many gains in patient pain care that have been made in recent decades. Pain remains the most common reason people seek health care, and has been considered an epidemic by the Institute of Medicine. In fact, the incidence of chronic pain in the U.S. is greater than that of diabetes, heart disease and cancer combined.

Chronic pain was estimated in a 2011 study to affect roughly 100 million Americans and to cost about $635 billion annually in treatment and lost productivity. This does not begin to reflect the toll that inappropriately treated, persistent pain inflicts on the individual, the family and the community at large. Inappropriate pain management can cause many secondary health impacts including an increased risk for complications; impaired recovery from injury or procedures; diminished quality of life; and a higher risk for anxiety, depression and suicide.

Opioids remain an important treatment option that can relieve suffering and improve patient function in some cases. It must be repeatedly emphasized that opioid analgesic therapy is but one tool that may be considered and used in the management of chronic pain. The disadvantages posed by the use of opioid medications must be weighed against the disadvantages of untreated or inappropriately treated pain, as is the case with other treatment options. Physicians and patients are provided with the best opportunity to alleviate pain when they have access to all of the tools in the toolkit.
CMA Recommendations

**Encourage the education of prescribers, policymakers and the public**

While education alone will not eliminate the inappropriate use of opioids, education can make a difference. CMA has invested in and promoted physician education regarding pain management, and will continue to do so along with other medical professional groups. Medical education (undergraduate, graduate, and continuing education) must be augmented by education in all sectors of society including patients, policymakers, and the public at large.

Evidence-based best practices for physician prescribing have been developed by the medical community and physicians can benefit from learning about new research as it continues to be used to help clarify and improve guidelines. Physicians who prescribe opioids should have access to up-to-date information on a wide range of issues, including how to:

- Provide treatment that meets the community standard of care (patient screening practices, follow-up care, etc.);
- Regularly evaluate and monitor patients to determine if they actually have a condition that requires medication, and if they are taking the prescribed medication or if they are misusing medication, and whether or not the treatment continues to be safe and effective;
- Educate patients about the dangers of using the medication outside of a medically prescribed regimen;
- Appropriately use patient agreements that require patients to comply with a strict set of rules in order to receive medications, including where and how often they obtain controlled substances, and may involve random drug testing;
- Watch for signs of “doctor shopping” and be prepared to use strategies to respond and treat such patients; and
- Manage the significant risks that can come with prescribing opioids.

California requires that physicians take continuing medical education (CME) on “pain management” and “the appropriate care and treatment of the terminally ill,” but the state can incentivize opportunities for physicians to increase their knowledge related to opioid analgesics in particular. Grants could be provided to support the development and use of voluntary CME related to opioid prescribing. Relevant licensing boards, including the MBC, could be directed to provide voluntary opioid related-education opportunities on a recurring basis. The “Medical and Pharmacy Boards’ Joint Forum to Promote Appropriate Prescribing and Dispensing” CME opportunity in February 2013 was well attended and could be repeated in other parts of the state. Another strategy is to have all or a portion of the fees DEA charges for controlled substance registration waived for prescribers who take relevant CME.

While nearly all physicians have DEA numbers and the ability to prescribe controlled substances, only a subset of DEA-registered practitioners prescribe opioid analgesics. CMA strongly encourages the availability of physician education, and believes that providing a diverse set of opportunities and materials is an important strategy for reaching physician prescribers.

CMA has been partnering with the American Medical Association (AMA) to promote trainings on opioid prescribing, as well as working with the Institute of Medical Quality to produce California-specific trainings. CMA’s Council on Scientific Affairs is producing a technical document that also represents a coordinated effort to help California physicians better understand the clinical issues related to responsible opioid prescribing. In addition, CMA has undertaken a major push to educate physicians about the importance of CURES and facilitate their registration in the system.

---

vi: Pathologists and radiologists are exempt.
It is also important that the public and policymakers also receive education about pain, pain management options and opioids. Physicians have some opportunity to educate their patients, but more general, scientifically-based information about these issues is needed so that all the stakeholders better understand their role in preventing misuse. California agencies can work with the physician community when developing materials for events, such as drug take back days, to build in accurate and educational messages.

**Obtain additional data on opioid misuse specific to California**

A great deal remains unknown about the risks of opioid pain medications and underlying causes of opioid misuse, as well as the degree of misuse that can be directly attributed to physicians. In particular, access to data specific to opioid misuse in California is limited. Gathering additional information, evaluating it, and sharing it with others are all critical. Aggregate measures from data sources such as CURES can help guide strategies to improve the effectiveness of the overall system.

---

“99.9% of practitioners... are doing exactly what they are trained to do – they are healers. They are protecting their patients.”

- Joseph Rannazzisi, Deputy Assistant Administrator, US DEA, February 21, 2013, Joint Medical Board of California and Board of Pharmacy Pain Summit

---

It is important to remember that the vast majority of physicians prescribe in good faith according to accepted standards of practice. Most law enforcement professionals understand that only a small percentage of physicians are criminals, yet the solutions some propose would negatively impact all physicians, and their ability to help patients manage and relieve pain. An evidence-based approach is needed to better understand the problems in California and develop potential solutions to target criminals, without imposing unreasonable and unworkable mandates on physicians.

To the degree possible, regulators should seek ways to acquire and publish data on opioids that helps identify the root causes of misuse. There is a general need for recognition that this problem is large and complex and there is great need for additional data. Some questions to consider when exploring the meaning and importance of future data are illustrated below.

---

**Questions to Explore**

A partial list of questions to explore when data is gathered or presented on prescription drug abuse in California.

**What is the reason for misuse?** Recreational? Misunderstood instructions? Didn’t like adverse side effects? Did not feel that pain was being appropriately treated as prescribed? Suicide?

**What was the nature of misuse?** Too much? Too little? Combined with contraindicated substances?

**What was the source of the misused substance?** Drug dealer in non-medical setting? Prescriber – legitimate and appropriate? Prescriber – legitimate but inappropriate drug or dose? Prescriber – illegitimate (i.e., pill mill)?

**How was the drug obtained?** Retail pharmacy? Internet pharmacy? Drug dealer? Given by friend or family? Sold by friend or family? Stolen from friend of family? Forged prescription?
Establish and fund a range of tools to improve patient safety

Many medical and non-medical tools and strategies can be used to address the issue of opioid misuse. As discussed previously, CURES is a public health tool that needs to be funded and improved with an emphasis on improving patient safety. The DOJ recently indicated that approximately $2 million is needed to modernize CURES, and that approximately $1,621,000 would be needed annually to staff, operate and maintain an upgraded system. Yet even if improved, the system would not be able to address many aspects of prescription drug misuse, such as the pills taken out of the medicine cabinet by a family member, or a legitimate patient who mixes their drugs with contraindicated substances.

Non-medical strategies to help stem opioid abuse need funding as well. For example, providing drug take-back opportunities and drug disposal education programs are essential. CMA has partnered with others to promote take-back events. The DEA recently issued proposed regulations that would expand the options available for states to collect controlled substances, and this change may not necessarily come with funding to pay for an increased state responsibility. California needs to think ahead about how to provide such services.

Fortunately, some potential strategies have been identified. As required as part of 2007’s California Senate Bill 966, CalRecycle provided related recommendations to the California Legislature on how the state could better support pharmaceutical waste collection programs. A 2010 progress report prepared by CalRecycle found that a lack of sustainable funding is a major barrier, and ultimately the agency recommended a series of statutory changes to establish clear state roles and responsibilities, and addressing funding barriers through a private sector approach with government oversight. The recommendations have yet to be adopted, but it is not too late for California to act.

In addition, quality substance abuse treatment programs are another key component of a comprehensive approach. There are a wide variety of promising community-based prevention and treatment programs. Increased funding and support for these programs are needed to ensure access.

Maintain the physician role in evaluating appropriate pain management and use of opioids analgesics

CMA has always supported a strong and effective process for investigating and prosecuting physicians who do not practice the accepted standard of care, and to that end, we advocate that the MBC should have the resources to support that work. However, “loans” and restrictions on filing positions have stymied enforcement efforts. In Fiscal Years 2008/09 and 2011/12, the Medical Board Contingency Fund made two loans of $6 million and $9 million to the State General Fund. To date, there has been no repayment of either of these loans totaling $15 million, and there is no due date in place for repayment. The MBC has also been subject to periodic hiring and spending freezes due to Executive Orders, which have impacted staffing.

Although the public is clearly not served by physicians who prescribe inappropriately or illegally, justice and due process are not served by an overly rapid system of investigation that assumes guilt before evidence proves otherwise. Ensuring due process is critical. The MBC needs to maintain a system that uses physicians with the appropriate expertise to review complaints and medical records during the investigation process in order to determine whether there has been a departure from the standard of care. How this important piece of the investigatory process would work under any new proposal is of utmost importance to CMA. Even if a complaint is found to be without merit, defending against these allegations can disrupt patient care.

It is also critical that the physician role in evaluating appropriate pain management not be limited by a standardized protocol, as it restricts treatment options. As discussed throughout this document, providing a wide range of treatment options maximizes the potential of pain management and recognizes the individualized needs of the patient. With extensive training, practice, and continuing education, physicians are willing and able to continue to take on the responsibility for patient care.
Summary

Physicians have a professional, ethical, and legal obligation to mitigate the effects of illness. Pain is no exception. Opioids are not panaceas. They seldom, by themselves, adequately address the complex issues that a patient with chronic pain faces. In addition, opioids have a wide range of potential adverse effects that can expose a patient to serious morbidity and even mortality. Nonetheless, opioids remain vitally important tools for alleviating suffering, promoting healing, and restoring function. A comprehensive approach to addressing this challenging issue is essential and the physician community pledges to do its part.
References


31. Federation of State Medical Boards of the United States, Model Policy for the Use of Controlled Substances for the Treatment of Pain, 2013.

32. American Academy of Pain Medicine, Safe Opioid Prescribing: Reversing the Trend Course.


