CSAM news
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THE VOICE FOR TREATMENT
NEWSLETTER OF THE CALIFORNIA SOCIETY OF ADDICTION MEDICINE

President's Message

Follow the Evidence

David Kan, MD

Over the years, I have found three types of evidence in the practice of medicine.

The first type is evidence-based practice. The evidence supports the practice and physicians act accordingly (e.g., insulin for diabetes and naloxone for an opioid overdose).

There is evidence-free practice. There is no evidence to support the practice, but we do it anyway. We provide education in addiction treatment, yet there is little evidence to support education as improving outcomes for patients who already have a substance use disorder.

The last piece of evidence is evidence-proof practice. The evidence for a particular practice is strong, but prevailing factors such as culture and the "ick" factor prevent adoption. Consider contingency management.

It is within this context that I approach our current view of opioids in the United States.

The 2016 CDC guidelines was a response to an overdose epidemic[1]. However, it has been one of the most misinterpreted guidelines resulting in inadvertent damage to our patients. The CDC guidelines have morphed from good guidance into evidence-free practice and evidence-proof practice. The 2016 CDC guidelines were intended for new opioid starts and not for the patient already on chronic opioid therapy.

The CDC recommendations around Morphine Milligram Equivalents (MME) were taken retrospectively from queries of the Washington State Worker's compensation database. Increased rates of overdose, both fatal and nonfatal, were identified after the fact and used to set parameters for "safe" dosing. However, none had examined at that time whether or not

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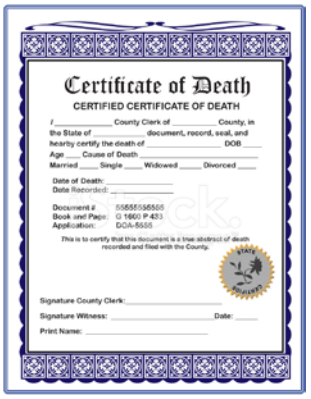
The Death Certificate Project

Medical Board of California's Use of CURES and Autopsy Findings

By Lee Snook, MD, Karen Miotto, MD, and Gail Jara



Since the Medical Board of California (MBC) launched its new case finding effort called the Death Certificate Project, hundreds of physicians received letters from the Medical Board requesting authorization to review their patient records. When you receive a letter like that from the licensing agency, it can feel like you are being threatened with disciplinary action.

HOW IT WORKS

Physicians who prescribed opioids to a now deceased patient with a death certificate that indicates the death was related to "prescription drug use" are receiving letters from the Medical Board requesting the patient's records and asking the physician to provide a summary of the care provided. The current focus on efforts to prevent opioid overdose deaths is seen as a need for this project.

The project unfolds in steps. This description of the process is derived from the Medical Board's podcast[1], transcripts of MBC meetings, and our discussions with physicians who received such letters and/or are being investigated as a result of this project. Here is what we learned.

- Pursuant to an interagency agreement with the California Department of Public Health (CDPH), the Medical Board received information on deaths in 2012 and 2013 related to opioid prescription drugs. The CDPH dataset received by the MBC in 2015, based on death certificate information, used a set of codes that CDPH used to identify the underlying cause of death and the contributing cause of death to identify opioid pharmaceutical-related deaths. The data identified 2,692 deaths that met the criteria.
- Once the data file was received, the MBC used the Controlled Substance Utilization Review and Evaluation System (CURES) database to identify physicians, who were prescribing to the individuals, as well as the attending physician and the physician who certified the death.
- The MBC would then send the CURES information to reviewers who make a determination if there may be inappropriate prescribing that warrants further investigation including requesting medical records from the prescribing physician.

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CSAM Leadership Development Retreat

June 7-9, 2019 | Asilomar Conference Center in Pacific Grove, CA

The CSAM Leadership Development Retreat is a biennial three-day weekend event for current and future CSAM leaders to network and gain new knowledge and skills. The retreat is designed to help you with your practice, as well as prepare you for a leadership position in CSAM.

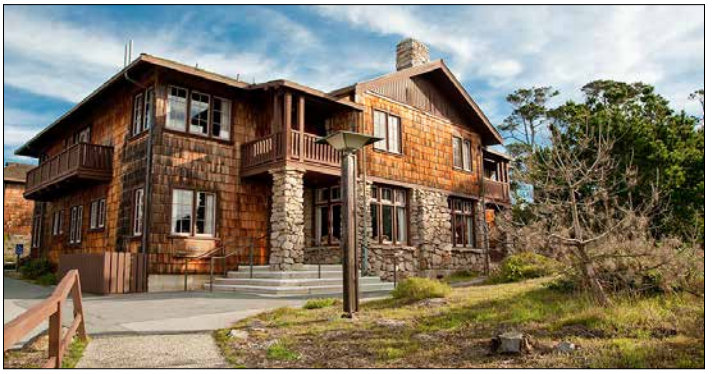
Join with your CSAM peers to:

- Understand what the future will hold for stimulants, opioids, and cannabis
- Develop your "pitch" on a variety of addiction subjects derived from ASAM and CSAM perspectives and unique to your delivery style. Articulate concise, focused statements to help you in your practice while advancing addiction recovery as a whole
- Plan your future with an eye on ethics, preserving your reputation and making a difference
- Help advance the mission of CSAM in offering education, advocacy for members and their patients; leadership in state and national roles; and access to high quality addiction treatment in California
- Discover new technologies relevant to our field to help you in your practice
- Network, share perspectives and connect during breaks and participate in option events throughout the days and evenings
- Gain an understanding of current policies and how to be a catalyst for change
- Help CSAM shape the future and implement its strategic plan

Asilomar Conference Grounds is located on a stunning beach and features historical architecture by renowned architect, Julia Morgan. Learn more at https://www.visitasilomar.com

CSAM Leadership Retreat 2017 Participants

CSAM Leadership Retreat Fireside Discussion



Accommodations are included in the Retreat fee.

Retreat Schedule: Visit the CSAM Leadership development retreat webpage to view the schedule: https://csam-asam.org/event/CSAM2019LeadershipRetreat

Fees: $950 fee includes two night's lodging at Asilomar, all meals and all activities including professional training/coaching sessions. Discounted price for early career physicians and a limited number of partial scholarships are available based on financial need.

Pre-requisite: You must have an active CSAM membership. To join, go to https://www.asam.org/membership.

If you are interested in becoming active in CSAM and attending this event, apply at https://csam-asam.org/event/CSAM2019LeadershipRetreat.

Questions? Email csam@csam-asam.org ■

CSAM Addiction Medicine Review Course and Board Exam Preparation Track 2019

By Tauheed Zaman, MD, CSAM Review Course 2019 Conference Chair

Tauheed Zaman, MD

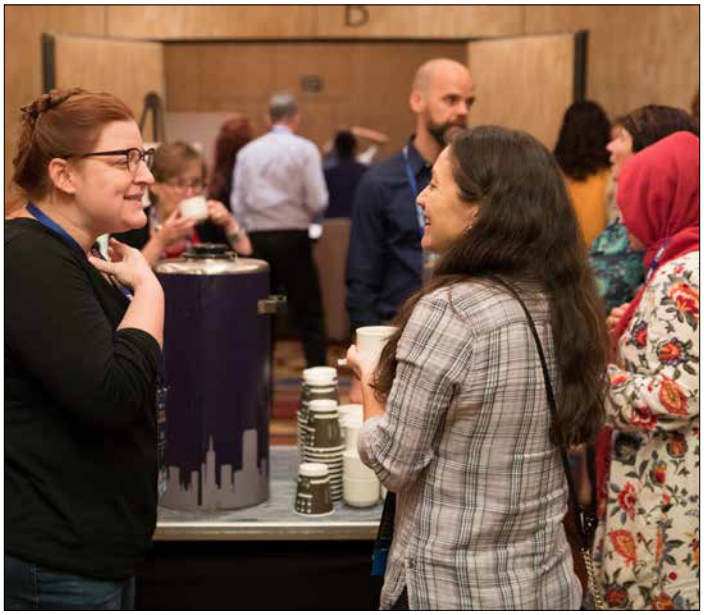
I am thrilled to invite you to the CSAM 2019 annual meeting in Anaheim, California on September 4-7.

This year, we get to carry on the tradition of presenting an excellent review of fundamentals ahead of the board exam—with a twist. Our conference features the theme "A Spotlight on Educators and Advocates." Speakers will discuss the ways they educate others about each addiction-related topic, and how they advocate for their patients. Two keynote speakers, a documentary screening, and a dessert reception will all reflect our theme in different ways.

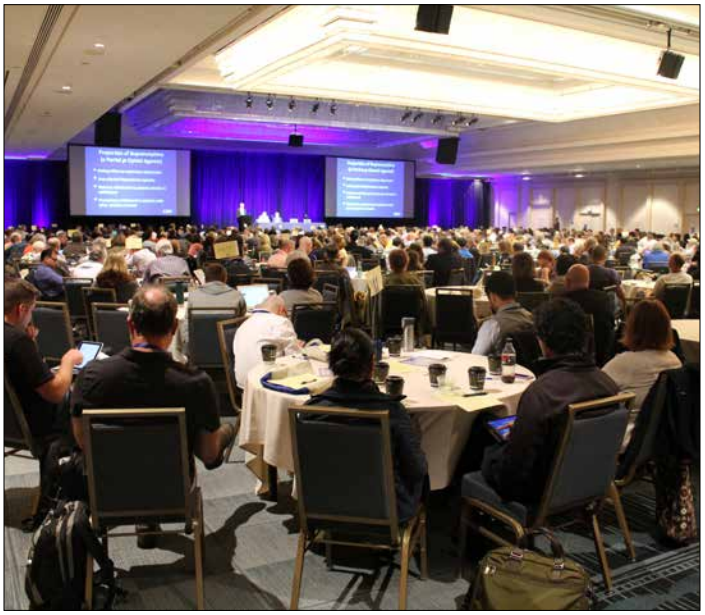
Our lineup of presenters includes addiction experts from a range of different practice settings. From fundamentals to advanced topics, their talks are designed to both educate and inspire learners at different stages of their careers. As usual, a dedicated team of table facilitators will guide conference attendees through teaching cases throughout the conference.

So whether you're preparing for the Addiction Medicine board examination, looking to solidify your own clinical knowledge, or simply looking to be inspired by a network of colleagues- look no further!

Please learn more and register today at csam-asam.org. We look forward to seeing you at the meeting. ■



2018 Conference participants networking



Review Course Presentation

Funding Provides Scholarships for Mentored Learning Experiences at CSAM Addiction Medicine Review Course

Partnering with the California Department of Health Care Services (DHCS), CSAM and its sister organization the Medical Education & Research Foundation for the Treatment of Addiction (MERF) have been increasing efforts to provide training and mentoring to physicians and other providers through California Medication Assisted Treatment (MAT) Expansion Project through scholarships.

Under the MAT Expansion Project, CSAM received scholarship funding in September 2018 to offer training and mentoring to 48 primary care providers through Mentored Learning Experiences (MLEs).

Scholarships provided these benefits:

- Full funding to attend the three-day CSAM Addiction Medicine State of the Art Conference in San Francisco.
- Opportunities to learn more about MAT, motivational interviewing, opioid dependence, and pain, minimizing diversion, behavioral interventions, co-occurring disorders, and innovative ways to reduce the barriers to treatment access.
- Small group discussion and mentoring by addiction medicine experts.
- Presentation and discussion of real life case studies in a facilitated roundtable format.
- Post-conference virtual meetings with expert providers to provide updates on new developments in MAT and on-going clinical support and guidance.

Through this project CSAM is:

- Reaching primary care providers in rural areas where the need is great
- Targeting at least one provider in their respective clinic to take on the role of "champion," or someone who encourages and supports other providers to treat opioid dependent patients
- Making inroads to normalize MAT so that more primary care physicians will want training
- Working to reduce the perception that one must jump through many extra hoops in order to prescribe buprenorphine
- Working to reduce the fear that comes with extra DEA oversight
- Helping overcome the perception by some physicians who are concerned about not having enough time or resources to help patients with opioid addiction
- Assisting primary care providers in overcoming barriers to doing drug testing
- Helping primary care providers navigate the system of Prior Authorizations required by some insurance carriers when prescribing MAT. (We are aggressively advocating for removal of these barriers.)
- Working to inform providers on the best ways to refer patients to local resources

Here is some feedback received from providers who received scholarships:

"This experience has actually made me realize that I should be practicing addiction medicine instead of just family medicine."

"There was no MAT training included when I was in my residency. I think all providers should receive MAT training including eligibility for waiver upon graduation."

"Without the scholarship, I would likely not have been able to attend and learn the things I did."

Based on the feedback CSAM is receiving, these providers are now prescribing and encouraging other providers to do the same. Many of them are becoming "mentors" or "champions" in their own communities. The objectives of this project are being accomplished.

CSAM is receiving additional funding from DHCS to continue this project for two more years. Mentored Learning Experience Scholarships will be offered in Anaheim in September 2019 and San Diego in September 2020. For more information about the MLE scholarships, contact csam@csam-asam.org today. ■

MERF medical education and research foundation for the treatment of addiction

CSAM President's Testimony at the Medical Board of California — *The Death Certificate Project*

David Kan, MD, president of the California Society of Addiction Medicine, urged the Medical Board of California (MBC) at their January 31 meeting to halt the Death Certificate Project and to undertake an investigative process to address adverse outcomes when patients are abruptly cut off of their painkillers or see their prescription strengths dramatically reduced. He told the MBC that in a recent survey of CSAM's 600 provider members, CSAM members reported seeing more and more patients moving to dangerous drugs like heroin and fentanyl as a result of forced opioid tapers; 50% reported an increase in illicit opioid use as a result of opioid tapers and 75% rated specialty pain care in their area as worsening in access and in quality. "We're seeing more and more patients who are being summarily abandoned in the name of 'safety.' What is safe about leaving a doctor's office care and turning to the streets for heroin and fentanyl?" he asked the Medical Board. Moreover, he said, the project's methodology appears to be judging physicians "on the knowledge that was known as long as eight years prior." Primary care doctors are no longer prescribing opioids, and their patients are being abandoned, he said.

The Medical Board's Executive Director Kim Kirchmeyer acknowledged the concerns of CSAM and others speaking out from the physician community. She said the project can be improved. Based on physicians' objections she said, "board staff believes some methodology changes need to be made that will eliminate some of the concerns that have been raised. For starters, board staff and its reviewers will now begin to examine death certificates from 2016 and 2017 for the next phase instead of reaching further back, as was previously planned, she said. That may provide a better sense of physicians' current prescribing practices. Kirchmeyer said that instead of looking just at the physician's prescription history for each deceased patient with a death certificate, the board will expand its review to the physician's prescribing practices for other patients "at that stage, and will look for red flags for potential inappropriate prescribing patterns."

CSAM

Full Transcript of CSAM Testimony to Medical Board of California

My name is Dr. David Kan and I am the president of the California Society of Addiction Medicine. CSAM is the largest state chapter of ASAM — the American Society of Addiction Medicine. CSAM represents over 600 physicians and healthcare provider members. We are among the first responders to the opioid epidemic we now face. I am here today to speak on behalf of our members and their patients.

We are observing that the actions now being taken to implement the Death Certificate Project are causing adverse outcomes in the patients we currently treat. As a result, we strongly recommend that the Medical Board halt the current investigation process until it aligns its policies directly with CDC Guidelines opposing involuntary opioid tapers and addresses the adverse impact this project is having on patient care.

Here is the basis for this recommendation. CSAM conducted a survey of its memberships and found:

- Our members reported forcing opioid tapers or witnessing forced opioid tapers as a result of actions targeting doctors as the "problem."
- Our members reported seeing more and more patients moving to dangerous drugs like heroin and fentanyl as a result of forced opioid tapers.
- More than 50% of our members reported an increase in illicit opioid use as a result of opioid tapers and 75% rated specialty pain care as worsening in their local practice area.

We are less than three years into our current knowledge of opioid prescribing with the 2016 CDC Guidelines, yet physicians are being judged on actions as long as 8 years prior with the knowledge known at the time.

We are seeing more and more patients every day summarily abandoned in the name of "safety." What is safe about a patient leaving a doctor's care and turning to the streets for heroin and fentanyl?

I have personally given talks about opioid safety to many physician groups at the state and local level. I have clearly heard the message that physicians fear Medical Board action if they continue to prescribe opioids, even if done appropriately. Primary care doctors are declaring that they no longer prescribe opioids.

Therefore, CSAM urges the Medical Board to suspend all investigations until the exact impact of the CDC Guidelines is known and necessary amendments to the project can be made. We believe amendments to the MBC Death Certificate project will result in better care and outcomes for the people we care about the most, our patients.

Thank you for this opportunity to speak. Please feel free to direct any questions to me personally or email: csam@csam-asam.org ■

Call for CSAM Board of Directors Nominations

The positions of **President-elect**, **Treasurer**, and **"At-Large" Director** are up for election in 2019. The CSAM Nominating Committee, chaired by Dr. Monika Koch, is accepting nominations from the membership.

This summer, all voting members of CSAM will be sent an electronic ballot and invited to cast a vote on the Nominating Committee's slate prior to 5:00 pm on **Thursday, September 5, 2019 during the CSAM Review Course in Anaheim**.

Should a member wish to nominate a member to serve on the CSAM Board of Directors whose name does not appear on the Nominating Committee's slate, he/she must write to CSAM by no later than August 5, 2019 with a petition signed by two percent (2%) of the voting membership. In the event one or more petitions are received, a run-off election will be conducted in person at the **CSAM Annual Business Meeting on Friday, September 6, 1-2:00 pm at the Anaheim Marriott, Anaheim, CA**. If no petitions are received within the allotted time period, the Nominating Committee casts a unanimous ballot for all uncontested positions and elected candidates will be announced at the Annual Business Meeting.

CSAM Board of Directors at their meeting in Marina Del Rey on February 9, 2019

CSAM Seeks Nominations for Annual Awards

CSAM is accepting nominations for its two annual awards: The Vernelle Fox Award and the Community Service Award. Both awards are presented during the CSAM Addiction Medicine Review Course in Anaheim, CA on Thursday, September 5, 2019 during the Dessert Reception.

Vernelle Fox Award

CSAM recognizes physicians who have made noteworthy and lasting contributions in line with the mission of the Society: contributions which improve the quality of health care services, increase communication and education among providers of care and add to the research on which the understanding of the field is based and on which the health care services are built. Because the Society has designated its second President (1974-1976), Vernelle Fox, MD, as the model against which future recipients will be measured, the criteria for selection will reflect the contributions and qualities for which she was honored in 1983 at the Society's Tenth Annual Meeting: an inquiring mind (contributions to the understanding of the field), courage (resolution, tenacity) and enthusiasm (energy for the positive.)

Community Service Award

An award established in 1985, previously referred to as the Achievement or Merit Award, became the Community Service Award over time. This award recognizes a non-physician who made outstanding contributions to the community. Since 1985, this merit-based CSAM award has been awarded to a wide variety legislators, activists, community leaders and others, all with one thing in common: they improved the lives of those suffering from the disease of addiction, and by doing so contributed a valuable service to the community.

For more information, contact CSAM Executive Director Kerry Parker at 415-764-4855. Nominations should include a recent CV and may be sent to: kparker@csam-asam.org ■

New Medication Assisted Treatment (MAT) Webinars in the CSAM Education Center
(free for CSAM members!) **cme.csam-asam.org**

California Bridge Program Offers Training and Assistance

By Hannah Snyder, MD, Co-Principal, CA Bridge Program, UCSF at Zuckerberg San Francisco General Hospital

Hannah Snyder, MD

Most patients with substance use disorders are not currently in treatment, however, they often present to emergency departments (EDs) and hospitals with acute medical and psychiatric needs. Those who treat addictions can recount many stories of patients who walk into an emergency department complaining of nausea, diarrhea and diffuse aches in obvious opioid withdrawal, are then given clonidine and ondansetron, and told to simply "stop using drugs." There are patients who are admitted to the hospital for endocarditis from IV heroin use, and soon go into withdrawal, so uncomfortable that they leave against medical advice after only one day of antibiotics. Then there are stable patients on buprenorphine for years, admitted for planned minor surgery, who have their buprenorphine stopped, and are later discharged on oxycodone, without buprenorphine, which increase the risk of return to opioid use.

From 2005 to 2014, opioid use disorder-related emergency department (ED) and inpatient visits increased by 99% and 64%, respectively.[1] For people who use drugs, studies have shown that in the one month after a hospital discharge, drug-related deaths increase 15 fold.[2] Multiple robust studies have shown that ED and inpatient buprenorphine initiations lead to higher rates of linkage to care than referrals alone. This makes the acute setting a unique opportunity to provide compassionate care and linkage to long-term outpatient treatment, thereby preventing discharge against medical advice and overdose mortality.

The California Bridge Program[3] (www.bridgetotreatment.org) is an accelerated training program launched by the Public Health Institute in early 2019 for healthcare providers to enhance access to 24/7 substance use disorder treatment in California communities hit the hardest by the opioid epidemic. It is in essence an extension of the ED-BRIDGE effort[4], which works to get Emergency Departments set up for buprenorphine treatment and referral, and Project SHOUT[5] (Support for Hospital Opioid Use Treatment) which helps hospitals begin providing buprenorphine and methadone services.

The California Bridge Program is leading important training and technical assistance across the state of California to prevent opioid overdose death and co-morbidities. With funding from the Department of Health Care Services, California Bridge is supporting 31 health care facilities across the state in doing this work. California Bridge Hospitals will be able to start medication-assisted treatment (MAT) in ED and inpatient settings, and also link their patients to outpatient long-term treatment. Any site across the country can use the California Bridge website[6] to access materials including ED and inpatient guidelines for starting MAT, acute pain management on MAT, training materials, and clinical tools.

Providers may worry that starting MAT in the ED and inpatient settings is prohibited. However, the California Department of Public Health recently published an All Facilities Letter (AFL) to address these misconceptions around hospital initiated MAT. Section 19-02.1 of this AFL[7] states that General Acute Care Hospitals (GACHs) and Acute Psychiatric Hospitals (APHs) "…may each treat an addiction to a narcotic drug, including using MAT protocols, under their respective facility license. Health and Safety Code (HSC) section 11217(h) does not require a GACH or an APH to also have a Center for Devices and Radiological Health (CDRH) license to provide addiction treatment." Patients admitted for acute medical or surgical issues may be started on MAT for the length of their inpatient stay, without an X waiver or special licensure. In the ED, providers may administer (not prescribe) MAT for up to 72 hours without an X waiver.

California is leading the country[8] by offering 24/7 access to evidence-based treatment in the acute care setting, and helping patients link to long-term recovery. Through this "any door is the right door" approach, more patients will access friendly, stigma-free medical care, as well as life-saving treatment, in the acute care setting. ■

1 https://hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.jsp
2 White S et al. Drugs-Related Death Soon after Hospital-Discharge among Drug Treatment Clients in Scotland: Record Linkage, Validation, and Investigation of Risk-Factors.; PLoS One. 2015; 10(11): e0141073
3 California Bridge Program announcement: http://www.phi.org/news-events/1564/california-bridge-program-selects-31-health-facilities-to-expand-mat-for-opioid-use-disorder
4 ED-BRIDGE: https://ed-bridge.org/
5 Support for Hospital Opioid Use Treatment (SHOUT): https://www.projectshout.org/
6 The California Bridge website https://www.bridgetotreatment.org/
7 All Facilities Letter (AFL), See p. 8 of this publication: https://www.cdph.ca.gov/Programs/CHCQ/LCP/CDPH%20Document%20Library/AFL-19-02.1.pdf
8 Vox article: https://www.vox.com/future-perfect/2019/1/8/18099534/opioid-epidemic-addiction-treatment-emergency-room-er-california

The California Department of Public Health's All Facilities Letter (AFL)

State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
State Public Health Officer & Director

GAVIN NEWSOM
Governor

January 30, 2019 AFL 19-02.1

TO: General Acute Care Hospitals (GACH)
Acute Psychiatric Hospitals (APH)
Chemical Dependency Recovery Hospitals (CDRH)

SUBJECT: Medication Assisted Treatment for Narcotic Addiction
(Rescinds AFL 19-02)

AUTHORITY: Health and Safety Code (HSC) section 11217(h)

All Facilities Letter (AFL) Summary

This AFL rescinds AFL 19-02 and clarifies licensing requirements for GACHs, APHs, and CDRHs related to Medication Assisted Treatment (MAT) for narcotic addiction.

The California Department of Public Health (CDPH) has received several inquiries regarding addiction treatment pursuant to HSC section 11217(h). GACHs, APHs, and CDRHs may each treat an addiction to a narcotic drug, including using MAT protocols, under their respective facility license. HSC section 11217(h) does not require a GACH or an APH to also have a CDRH license to provide addiction treatment.

If you have any questions about this AFL, please contact your local district office.

Sincerely,

Original signed by Heidi W. Steinecker

Heidi W. Steinecker
Deputy Director

Center for Health Care Quality, MS 0512 ● P.O. Box 997377
Sacramento, CA 95899-7377
(916) 324-6630 ● (916) 324-4820 FAX
Department Website (www.cdph.ca.gov)

The Death Certificate Project

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- For the records identified with suspected inappropriate prescribing, the Medical Board may contact the next of kin of the deceased and ask permission to receive the medical records. If the family does not respond, the law allows the Medical Board access to the records, and the Medical Board sends a letter to the prescribing physician asking for the medical records and a summary of the care provided.
- The patient records and the summary of care go to a Medical Board expert reviewer who provides an opinion on whether a departure from the standard of care has occurred.
- Based on the expert reviewer opinion and other evidence, the Medical Board may file an accusation and the MBC investigation proceeds as it does for any other accusation or complaint sent to the MBC.

It was noted at the MBC meeting "that the experts had found that in general, providers were writing for high-doses of opioids in combination with one or more sedating drug, such as benzodiazepines, Soma, and sleeping pills." The MBC meeting notes say that the reports from the MBC experts emphasized that the CURES report on these providers revealed that it was common to see many other patients in their practice receiving the same combination who are at risk for harm.

As mentioned above, the MBC meeting minutes show that, for the initial two years being investigated (2012 and 2013) MBC personnel found 2,692 deaths identified on the death certificate as related to prescription drugs, and the CURES data was reviewed for those 2,692 patients. Out of the 2,692, 84% (2,256 cases) went on to the next step in which the CURES data was sent to an expert medical reviewer.

Subsequent to these reviews, the Board identified 522 cases that required further information to determine if there was "inappropriate prescribing." The Board sent letters to these physicians requesting authorization to review their medical records. The physicians whose records were requested faced months of waiting for the results from the Medical Board's review – which we know is an unnerving experience.

Ten accusations have been filed to date. The Medical Board's Executive Director Kimberly Kirchmeyer said in the podcast that some of those physicians were already under investigation – investigations that had started before the Death Certificate Project.

CONCERNS

There are several areas of concern about the implementation of the Death Certification Project that should be of interest to all prescribing physicians. Primary among them is what constitutes standard of care. The MBC defines standard of care as "the level of skill, knowledge, and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstances at the time in question". The standard of care is determined from testimony of experts -- physicians who apply their experience, training and judgment to practice the art and science of medicine.

A troublesome feature of this project is that the Medical Board's expert reviewers often apply today's current thinking and practice recommendations to yesterday's records. However, practice patterns around prescribing opioid analgesics have evolved. For example, in 2012, equal-analgesic dose conversion charts were common to aid in converting from one type of opioid formulation to another. More recently, morphine milligram equivalence (MME) or morphine equivalence dose (MED) charts and calculators have been used to provide a comparison of different opioid medication based on a risk stratification adopted by the Centers for Disease Control (CDC) in 2016. Several factors related to opioid prescribing as well as the standards of care for pain management have changed:

- The MBC Treatment Guidelines for Prescribing Controlled Substances for Pain (November 2014) allows for patient and clinician variability
- The CURES database had limited functionality and was not routinely used in 2012
- MME or MED was not in common usage as an indicator of risk in 2012
- The measure of MME has limited scientific validity in chronic pain treatment
- The MME in common use today are derived from statistical analysis of "deaths"

There is also a major concern about how the death certificates identify the cause of death. We do not have a definition of the criteria used to enter into the autopsy data that the "patient died of a prescription overdose."

In addition, our concerns include the following points and they should be addressed in a review and analysis of the project:

- Coroners in California are not required to be licensed physicians or forensic pathologists, therefore the cause of death may not have been determined by a physician or other health care professional. Unlike 16 other states, in California coroners do not need to have any formal training in death investigation.[2]
- Many necropsy findings are used to assign cause of death without including pre-mortem data, such as the "blood levels" of prescribed medications.
- The "normal" blood levels ranges reported by the reference lab do not apply to chronically administered medications.

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President's Message

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patients did better as they were tapered off of opioids. Analogously, retrospective evidence with expert consensus previously led us to the conclusion that peanut exposure caused peanut allergies.[2] Thus, pediatricians recommended avoiding peanuts. Unfortunately, being a compliant parent, I had kept peanuts from my now nine-year-old son as an infant. He now has a peanut allergy.

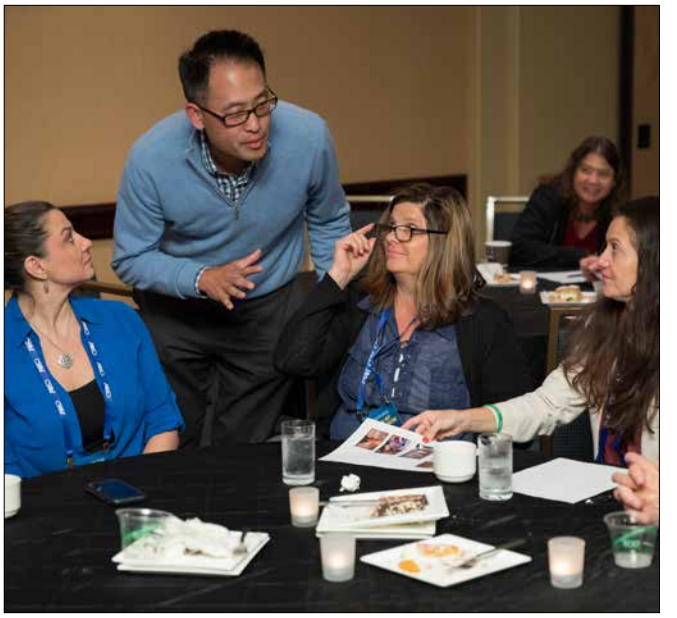
Based upon multilevel implementation of the CDC guidelines (health plans, pharmacy chains, group practices), we as addiction specialists have seen a spike in untoward outcomes. A survey of CSAM members has born witness to the effect of forced opioid tapers in our patients. We have seen decompensation, migration to more dangerous drugs, untreated pain, and emergency room visits rise. The scientific literature is beginning to mirror what CSAM members have seen in clinical practice.

Research has shown that prescription monitoring programs will likely lead to an increase of 40,000 deaths over the next ten years.[3] Efforts to reduce prescription opioid misuse alone will do little to halt overdose deaths.[4] Efforts to blame physician prescribing are counterproductive in stemming the tide of overdoses that promises to increase for the next 10 or more years.[3]

Furthermore, the Medical Board of California (MBC) has initiated the Death Certification project that, until now, has not been known to most physicians but is now having impacts in producing physician fear. Fear makes physicians not think straight. Fearful physicians hew towards "safety" and "safety" means not prescribing opioids, even when appropriate. I know of at least one program in California who has avoided prescribing buprenorphine for opioid use disorders (OUD) because of the MBC Death Certificate project. There are probably many more X-waivered providers upon learning of the MBC Death Certificate project who will not turn their "X" into an Rx for a patient in need.

We must stand in opposition to practices that will ultimately harm our patients. We must promote practices that will help our patients. The most important interventions to keep our patients alive amid an overdose epidemic include naloxone availability, medications for OUD, counseling, safe consumption/injection facilities, and needle exchange.[1]

We must no longer let fear and expert opinion cloud our thinking. We must follow the evidence. Good ideas are a start, but until the evidence is there to support good ideas, we should not let good ideas alone radically shift our practices until the impacts are fully understood. Let us follow the evidence that will actually save our patients' lives. ■



CSAM President David Kan, MD is Chair of CSAM's Opioids Committee and a presenter at CSAM's 2019 Review Course

[1] https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm

[2] https://www.ncbi.nlm.nih.gov/pubmed/27820622

[3] https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2018.304590

[4] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405

The Death Certificate Project

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- In clinical practice, physicians monitor urine, not blood, for drugs, utilizing qualitative, quantitative and point of care testing. Urine levels of opioids do not correlate with how much one has taken or how recently; studies have demonstrated that the same dose across a large numbers of subjects show a broad variety of urine drug levels due to individual variations in metabolism and other factors.[3]
- Autopsy reports have many reasons for a possible "sudden death" which may not be taken into consideration when the "cause" is ascribed to an "overdose."

REVIEW AND ANALYSIS NEEDED

The Medical Board's Death Certificate Project has been undertaken to identify physicians whose prescribing patterns are designated by the MBC expert reviewers as placing patients at risk for overdose death. The project, with its laudable mission and purpose, should be treated as a pilot and should be the subject of on-going evaluation and modification in areas such as these:

1. Before a death is deemed by a coroner to be 'caused by prescription drug use', the criteria for aberrancy in prescription drug use and/or prescribing ought to be determined. What information surrounding a death should be reviewed before identifying a death as being 'caused by prescription drug use' and which types of prescriptions are problematic?

2. Reviewers should use criteria specific to the prescriber's practice of medicine. The amounts of opioid medication prescribed, for instance, will be different if the physician is in palliative care, pain management or primary care, for example. Expert reviewers should consider the unique clinical context of each case before determining aberrancy or negligence by the prescriber. For example, a comprehensive medical record review, often not performed in a coroner's report, may provide critical information that would influence a more accurate determination of the possible causes of death.

3. Expert reviewers should view treatment guidelines as suggested clinical practices and should be mindful of the unique clinical context in the case being reviewed. Consideration of the clinical context should outweigh strict adherence to treatment guidelines.

4. Clarification of the limitations and purposes of the CURES database should be provided to each expert reviewer, including the understanding that the CURES database is not considered a forensic document, but rather a clinical tool. The clarification should take into account the fact that not all substances including medications such as methadone for treatment of a substance use disorder in an opiate treatment program (OTP) are entered into CURES. The clarification should include cautions about how to apply the information entered into the CURES database prior to 2018 because we know that the database was not in full implementation until October of 2018.

5. Although it is true that risks increase with prescribing any combination of an opioid, benzodiazepine, and a muscle relaxant, and that prescribing any combination of these drugs may in certain circumstances warrant an investigation by MBC identified experts, their use is not de facto "inappropriate prescribing."

6. There should be specific training for those who will render an overdose determination on a death certificate. There are acknowledged concerns about the quality/validity of the data entered on death certificates. It is known that the documented cause(s) of death may be varied depending on the coroner's level of training and the definitions they use.

FINAL COMMENTS

There is a danger of a paradoxical effect or unintended consequence of the MBC Death Certificate Project as it is currently being implemented. It may diminish access to care or prevent some patients from getting care. It may discourage some specialists from using their experience and expertise in employing the flexibility needed to care for complex patients. It may cause some physicians to stop prescribing opioids altogether and to avoid the risk of caring for patients receiving opioids and/or other controlled substances as part of their ongoing care. It may mean that some patients will not be able to find a physician. These patients are vulnerable and often the sickest of the sick. They are among the most challenging patients and not all physicians are willing to undertake their ongoing care. Standards of care specific to the prescriber's specialty and practice should apply to those physicians who are willing.

An analysis of the effectiveness of the Death Certificate Project should include a cost/benefit analysis to weigh the consequences and costs against the benefit to the public. Until then, we need to proceed with utmost caution and align public protection with the physician's calling to help the sick and suffering. ■

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[1] See the *MBC Newsletter* Spring 2018 page 4 for the link to the podcast in which Kimberly Kirchmeyer, Executive Director of the Medical Board of California, describes the Death Certificate Project. http://www.mbc.ca.gov/Publications/Newsletters/newsletter2018spring.pdf

[2] In California, coroners are not required to be physicians or forensic pathologists nor are they required to have any special training. However, in 16 other states, laws mandate specific death investigation training for coroners. Four states require coroners to be physicians (Kansas, Louisiana, Minnesota, and Ohio). https://www.cdc.gov/phlp/publications/coroner/training.html

[3] See *J Opioid Manag*. 2009 Nov-Dec;5(6):359-64. Use of an algorithm applied to urine drug screening to assess adherence to an oxycontin regimen. Couto JE1, Webster L, Romney MC, Leider HL, Linden A: https://www.ncbi.nlm.nih.gov/pubmed/20073409

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