THE DEATH CERTIFICATE PROJECT:
A Prescription for Litigation

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INTRODUCTION

The Medical Board of California's "Death Certificate Project" is, indeed, as ominous as the name suggests. The United States is currently experiencing a harrowing opioid epidemic with thousands dying annually from overdoses, largely from traditionally marginalized and vulnerable patient populations such as minorities and veterans. The Death Certificate Project ("Project") was the Medical Board of California's ("Board") response. The premise is simple: review death certificates, see who died from an opiate overdose, trace records back to the prescriber, and review for potential prescribing malfeasance.

While well-intentioned, this approach has raised concerns regarding patient privacy, upset families of the deceased, disquieted physicians specializing in pain management, and raised significant debate within the greater medical community.

BACKGROUND

The Death Certificate Project finds its origins in 2013. At that time, Senator Price, former Chair of the Senate Business and Professions Committee, introduced Senate Bill (SB) 62.[1] SB 62 forced coroners to report deaths resulting from prescription drug overdoses to the Board. The reports were intended to be comprehensive, providing enough identifying information that the Board could launch its own investigation into the death. The Bill notably did not require coroners to make any determination as to whether the prescribing physician was negligent in his or her prescribing, or whether their treatment fell below the standard of care. According to Kimberly Kirchmeyer, Executive Director of the Board, this was done purposefully in an effort to encourage coroners to report overdose deaths freely to the Board, without the burden of placing blame on a particular physician. It is of note that, notwithstanding SB 62, coroners are required to report pathology findings to the Board if they indicate gross negligence.[2]

SB 62, however, was ultimately vetoed because its implementation would have created an unfunded mandate. Its termination was the catalyst for the Board's Death Certificate Project. After SB 62's rejection, Board staff collaborated with the Senate Business and Professions Committee to develop a plan that would allow the Board access to the same information sought under SB 62. It was determined that since the California Department of Public Health ("CDPH") is responsible for gathering all death certificate information, CDPH could serve as a conduit between coroners and the Board. After several months of negotiations, CDPH and the Board signed an interagency agreement, and CDPH began providing the Board information regarding deaths from the years 2012-2013.[3]

Currently, through the interagency agreement with CDPH, the Board reviews California death certificates where the cause of death was determined to be an overdose of opioid pain medication, or where opioids were noted as a contributing factor.[4] The Board then reviews the Controlled Substance Utilization Review and Evaluation System ("CURES"), maintained by the Department of Justice,

to determine which physicians prescribed the deceased opioids ever, not just at the time of death.[5]

A subsequent investigation ensues to determine whether the opioid prescribing was within the standard of care. Typically, physicians can expect to receive a subpoena in such cases, requesting additional medical records of the decedent which are then reviewed by a Board expert. The decedent's family is also often interviewed during the course of the investigation. If there is evidence of overprescribing, the Board can, and has, filed accusations against the subject physician seeking license revocation.[6]

As to the Board's initial application of this process, according to Carlos Villatoro, Public Information Officer for the Board's Executive Office:

> *"Consumer protection is the Board's mission and the Board takes that mission very seriously. In reviewing the death certificates for overprescribing, the Board's physician experts are reviewing information to determine if the physician acted within the standard of care. In August 2015, the Medical Board of California (Board) obtained approximately 2,700 public death certificates from the California Department of Public Health (CDPH) with deaths related to opioid prescription drugs. The Board utilized experts and the Department of Justice's Controlled Substance Utilization Review and Evaluation System (CURES), to determine if there were potential inappropriate prescribing patterns. The Board identified 450 patients who may have received inappropriate prescribing by physicians and referred 72 additional cases to other licensing boards, such as the Osteopathic Medical Board of California and the Board of Registered Nursing. The Board then obtained medical records for the patients and began investigating the deaths using its normal enforcement process."*[7]

In 2017, once the Board identified the 450 patients noted *infra*, letters were first issued to physicians and other health professionals seeking certified medical records of the decedents. The Board received significant criticism regarding the initial correspondence to providers, as many viewed the letters as misleading and hostile. Based on complaints from consumers and providers, the Board revised subsequent letters, beginning in the summer of 2018.[8]

The Board's form letter to providers who are under investigation pursuant to the Project now have a vastly different tone, stating in pertinent part, "Please be aware that the Board understands that just because a patient death occurred, it does not automatically mean the physician deviated from the standards of care or otherwise violated the Medical Practice Act…Please be aware that this initial review is not public and is not posted on your physician profile…." The correspondence goes on to reference newsletter enclosures entitled, "Do Not Panic! What Should You Expect if a Complaint is Filed Against you?" and "What Should You Expect if There is an Investigation after a Complaint has been Filed?" While the new letters emphasize the routine nature of the inquiry, the bottom of the respective letters does cite, in bold, to statutory penalties for not providing the requested medical records under the Medical Practice Act.[9]

MEDICAL COMMUNITY RESPONSE

This Project has caused fear among clinicians, resulting — as some have expressed to the Board — in a decrease in physicians prescribing opioids even when they are clinically appropriate. Some physicians also feel the project is unfair based on previous guidance from the Board, who actually advocated opioid prescribing in the early 2000's.

During the Board's January 31, 2019 quarterly meeting, Dr. Phillip Coffin, Director of Substance Use Research in the Center for Public Health Research at the San Francisco Department of Public Health, stated:

> *I've heard multiple reports of providers who have outright stopped prescribing opioids due to fears about the Board's Death Certificate Project…I've also heard about families traumatized by calls from the Board…Providers and administrators do not want to take on the added risk of Board investigation in order to care for a population that is already perceived as challenging and extremely stigmatized…To have prescribers stop prescribing out of fear for their license and worse yet, to have them not be willing to treat the opioid use disorders that we as a medical community created based in part on the Board's requirements*

to take CME's advocating opioid prescribing, that was often industry funded, is dangerous to patients and frankly violates the ethical principles of medicine. I strongly urge the Board to discontinue the Project which is unintentionally harming patients.[10]

The sentiment that patients are being harmed by the Project, rather than protected, was echoed during the same Board meeting by Dr. David Kan, President of the California Society of Addiction Medicine (CSAM). Dr. Kan noted results from a recent CSAM survey:

> *[Physician] Members reported witnessing forced opioid tapers, or forcing opioid tapers themselves 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...I've clearly heard the message that physicians fear a Medical Board action if they continue to prescribe opioids, even if done appropriately.*[11]

Following Dr. Kan, Dr. Edward Machtinger, Professor of Medicine, Director of the Women's HIV Program (WHP) and Director of the Center to Advance Trauma-informed Health Care (CTHC) at the University of California, San Francisco (UCSF), emphatically stated:

> *"Here's the problem. The Death Certificate Project is creating panic among frontline clinicians who treat patients with complex health and social conditions. Providers are scared that one of their patients will overdose, for reasons totally out of their control, and that they will be humiliated or worse by this Board if they had prescribed opioid pain medicines for them...Many providers are now simply refusing to accept any new patients that are on chronic opioids for their chronic pain...The patients that I see being adversely affected by the Death Certificate Project are predominantly African American, Latino, or from other minority groups. This racial disparity isn't surprising, it's well that providers of medical care in general have implicit bias that leads to broad assumptions that an African American or Latino individual is more likely to be abusing drugs independent of any other objective factor. It shouldn't surprise us that anything that increases fear and panic among providers will increase the impact of this bias and lead to even worse outcomes for California's minority populations.*[12]

The Board was asked for this article whether it recognizes that the Project could make some physicians wary of prescribing controlled pain medications even when medically necessary. The Board issued the following statement in response:

> The Board is aware of physicians' concerns regarding the prescribing of opioids, however, the Board expects all California physicians to follow the standard of care for their patients and treat them with opioid medication if it is within the standard of care. The Board's goal with the death certificate project is to meet its mission of consumer protection by ensuring that physicians are following the standard of care when treating their patients. The Board has Guidelines for Prescribing Controlled Substances for Pain that assist physicians when treating patients with pain.[13]

RECENT DEVELOPMENTS

According to the Board, as of August 2019, there have been 512 cases opened against 469 physicians. 74 cases have resulted in an accusation being filed against 64 physicians (some physicians had more than one patient case lodged against them, which were subsequently consolidated into one accusation per physician). In addition, the Board issued two pre-accusation public letters of reprimand.[14]

The process to reach final resolution with respect to an accusation is quite lengthy, thus most of the accusations filed as of August 2019 are still pending. However, there have been a total of 5 licenses surrendered thus far, 6 physicians have been placed on probation, and 8 post-accusation Public Letters of Reprimand have been issued. Only 2 accusations have been withdrawn or dismissed.[15]

When asked whether the Medical Board intends to permanently continue the Death Certificate Project, the Board's representative stated:

> *The Board has determined that the death certificate project is a valuable method to identify physicians who may be inappropriately prescribing. With the first phase of the project completed, the Board will turn its*

focus to subsequent years and has employed lessons learned to improve the project. The Board is seeking to obtain public death certificates from CDPH for prescription related deaths occurring in 2016 and 2017.

However, "The Board does not have groups or committees overseeing the project at this time."[16]

It's also important to note, that when directly asked whether the Board has seen any statistical impact on the opioid epidemic since instituting the Project, and whether the Board is evaluating how well the Project is effectuating its mission, the Board stated, "The Board does not have statistics... The Death Certificate Project is a method for the Board to obtain information about potential inappropriate prescribing, which furthers the Board's mission of consumer protection."[17]

As the Board has only as of late begun issuing accusations resulting from Project investigations, precedent setting cases and guidance for attorney advocates is sparse. However, three cases have recently emerged which shed light on how the courts are approaching similar cases.

In February 2019, in *Grafilo v. Cohanshohet*, the Board sought an order compelling production of medical records from a physician of patients who were prescribed opioid doses that the Board suspected may have exceeded those recommended pursuant to the applicable standard of care.[18] The Court of Appeal held that the Board, whose supportive documents included an anonymous complaint, a declaration from its own expert, and a CURES report, had insufficient evidence to show good cause to compel compliance with subpoenas. The Court noted, "The Board is authorized to issue a subpoena in "any inquiry [or] investigation" (Gov. Code, § 11181, subd. (e)), and may do so for purely investigative purposes; it is not necessary that a formal accusation be on file or a formal adjudicative hearing be pending."[19] However, the Court held that the Board must *still* have good cause in order to obtain records pursuant to an investigatory subpoena, and facts suggesting that unusually high doses of opioids were prescribed to a patient, or a small portion of patients, is *not* sufficient to give rise to an obligation under a subpoena.

The Court stated,

[T]here are no facts suggesting Dr. Cohanshohet was negligent in treating his patients or that he prescribed controlled substances without meeting the standard of care. Given that Dr. Cohanshohet is a pain management specialist who sometimes treats patients seeking active cancer treatment, palliative care, and end-of-life care, it is reasonable to assume at least some of his patients would require treatment for pain that would exceed the recommended dose. Indeed, there is no indication how many patients Dr. Cohanshohet treats in total and what percentage the five patients at issue comprise that total.[20]

The court confirmed that "[G]ood cause is required to be shown when the state seeks to invade an individual's privacy rights through an administrative subpoena seeking his or her medical records."[21]

Following *Cohanshoehet*, in April 2019 the Medical Board filed a petition seeking to compel another physician to comply with a subpoena *duces tecum*, which sought patients' medical records in conjunction with an investigation into whether a physician was overprescribing controlled substances after receiving a complaint regarding five patients from an officer with the Ventura County Interagency Pharmaceutical Crimes Unit.[22] In *Grafilo v. Wolfsohn*, the Court relied heavily on the holding in *Cohanshoehet*, noting:

[T]he defects in the evidence supporting the subpoenas in Cohanshohet are present here and there are no additional facts that add substantial weight in favor of the subpoena. The DCA offered no evidence as to how many patients Wolfsohn treats, the percentage of his patients the five patients comprised, how often similarly-situated pain management specialists might prescribe the drugs Wolfsohn prescribed, or the likelihood Wolfsohn properly issued the prescriptions. Indeed, the DCA did not offer any evidence to contradict Helm's statement that Wolfsohn's prescriptions are 'not outside of acceptable' levels for a pain management specialist.[23]

In *Grafilo v. Soorani*,[24] a psychiatrist was investigated by the Medical Board after it received information that he was overprescribing controlled substances. The Board obtained a CURES report detailing his prescribing history. The

Board's medical consultant identified six patients who were prescribed controlled substances in large quantities or with "erratic patterns." The consultant opined it was necessary to review the medical records of those patients to determine whether the physician was excessively prescribing controlled substances. None of the patients granted the Board's request to access their records, so the Board issued subpoenas to the physician, who invoked patient privileges and privacy rights and refused to provide records.

The Board petitioned for an order compelling production of the medical records. The petition was supported by the consultant's declaration stating that the physician appeared to be prescribing medicine outside the standard of care and that obtaining patient records was the only way to confirm it. The superior court granted the petition, acknowledging patients' privacy interest, but finding disclosure justified by the state's interest in ensuring that medical care conforms to the standard of care. The superior court found that while the consultant's declaration did not prove that a violation occurred, it furnished sufficient reason to suspect it. The physician appealed.

The Court of Appeal affirmed, holding that the Board made a sufficient factual showing to justify the invasion of patient privacy. The court rejected the physician's arguments that the Board ignored less intrusive means of obtaining information (since it had asked for voluntary production); that the consultant was unqualified (since every physician can opine on standard recommended dosages and possible side effects of prescription drugs to the extent necessary to identify unusual prescribing practices at the outset of an investigation); and that the Board's consultant's declaration was speculative and lacked evidentiary support (since the consultant recounted specific prescribing irregularities involving high dosages and large quantities of drugs that had dangerous side effects). The appellate court affirmed the trial court finding of good cause to enforce the subpoenas.

These cases may prove informative in Death Certificate Project cases. In *Wolfsohn*, the court did state, however, "Evidence that a physician's patient has been harmed as a result of prescriptions issued by the physician would also weigh heavily in the state's favor in seeking patient medical files." Thus, it is reasonable to assume that the ability to demonstrate good cause for a subpoena of records would diminish substantially the more time there was between the treating physician's opioid prescription and the patient's death. It is important to note that some accusations filed involve patients who died a substantial period after the accused physician stopped treating the patient.

INVESTIGATION AND ACCUSATION RESPONSE STRATEGIES

In these types of cases, the best defense may begin at the investigatory stage, pre-accusation. If your client receives a subpoena for records, review the case thoroughly before advising him or her to comply. It may be worthwhile to object to the subpoena in light of *Cohanshoehet* and *Wolfsohn,* particularly if there is significant time between the date of the decedent's death and the last time your physician-client treated the decedent. The burden would then rest on the Medical Board to prove good cause, which would likely be difficult without further documentation. Bear in mind that once the Medical Board has the respective records, good cause for further requests is much more likely to be found, and your client will be unable at that point to close "Pandora's Box," placing the client at a much higher risk for an accusation.

Once an accusation has been filed post-Project investigation, it is vital that attorneys and their physician-clients are familiar with the statutes that directly affect relevant defenses. For purposes of accusations filed in relation to the Project, pertinent statutes worthy of review include:

Business and Professions Code § 2241.5 ("Intractable Pain Treatment Act"):

"A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain....No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section."[25, 26]

Business and Professions Code § 2241:

"A physician and surgeon may prescribe, dispense, or administer prescription drugs, including prescription controlled

substances, to an addict under his or her treatment for a purpose other than maintenance on, or detoxification from, prescription drugs or controlled substances… [A] person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict within the meaning of this section or Section 2241.5."[27]

Health and Safety Code § 124960 (Patient's Bill of Rights):

"A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with Section 2241.5 of the Business and Professions Code."[28]

Health and Safety Code § 124961:

"A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve the patient's pain, as long as that prescribing is in conformance with Section 2241.5 of the Business and Professions Code."[29]

The Board has made it clear that in filing accusations under the directives of the Project, the standard of care applied is relative to the timeframe of the respective prescription at issue. For example, if a physician is accused of overprescribing in 2012, the physician would be held to the standard of care in effect at that time. Thus, it is important in defending these allegations that an expert is retained that is not just versed in the current standard of care, but is intimately familiar with the timeframe at issue and the subsequent standard of care evolution. It has been noted that many of the Board's accusations contain substantial reference to CURES reports, and whether or not the accused physician checked the CURES report of the patient prior to prescribing. The standard of care with respect to CURES reports has evolved substantially since its inception to present. While statutory mandates do not necessarily equate to an applicable standard of care, physicians were not required to check the CURES database prior to prescribing until October 2018.[30] Moreover, in its early stages, CURES was notoriously unreliable. In fact, once the state passed legislation mandating CURES usage, its rollout had to be delayed because the system was unable to handle widespread usage.[31]

Further, be cautious with respect to the statute of limitations. Some accusations issued have referenced cases beyond the statute of limitations for prosecution, using them to indicate a pattern of conduct.

Finally, be prepared to comb medical records with respect to the subject decedent's medical background and treatment prior to the relationship with the accused physician. The decedent may have had longstanding issues which would be relevant to the accusation prior to seeing the accused physician. For example, if a physician is accused of overprescribing, the decedent's prescription history prior to seeing the accused physician is of high importance. It is also important that attorneys and physician-clients be aware that additional patients can be added to a filed accusation; there have been accusations filed by the Board under the Project with multiple patients at issue.

PROACTIVE APPROACHES

For attorneys with ongoing representation of pain management specialists, there are some proactive strategies that can be implemented to assist in avoiding future issues related to the Project:

1. Have a clear, documented, medical record retention policy in compliance with the law.
2. Obtain a thorough medical history when acquiring new patients that are on, or will need, opioid pain management. Request medical records from prior providers.
3. Keep abreast of Board guidance on prescribing; make sure pain management physicians have the latest guidance if they do not already.
4. Be familiar with Centers for Disease Control and Prevention ("CDC") guidelines on opioid prescribing. Document how medical decisions comply with CDC and Board guidelines; document the reasoning in the medical records.

In October 2019, the U.S. Department of Health & Human Services published the "HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics." Ensure that all pain management physicians are versed in this guidance and cite to it appropriately in their medical records.[32]

MOVING FORWARD

As noted, the Board intends to continue the Death Certificate Project and is currently working with CDPH to obtain death certificates from the years 2016-2017. Consequently, it is clear that the Project is, for the foreseeable future, here to stay.

Healthcare attorneys should be prepared to handle these unique cases; given the Board's statement noted infra, it is highly likely there will be another influx of accusations once the 2016-2017 death certificates are reviewed. Additionally, attorneys should be proactive in advising their established physician clients how to avoid future licensing issues with respect to their prescribing of scheduled narcotics.

Ultimately, the Board is attempting to effectuate its mission to protect health care consumers, "…through the proper licensing and regulation of physicians and surgeons and certain allied health care professionals and through the vigorous, objective enforcement of the Medical Practice Act…."[33] While some disagree with the Project's approach, in reality it is a tool the Board will continue utilizing, so attorneys and providers need to be prepared to respond.

ABOUT THE AUTHOR

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END NOTES

1 https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201320140SB62

2 https://www.mbc.ca.gov/About_Us/Meetings/Minutes/22/enf-Minutes-20170727.pdf

3 *Id.*

4 http://www.sfmms.org/news-publications/sfmms-blog/medical-board-requests-for-patient-records.aspx?PostId=4137&tabid=2622

5 California Regulatory Law Reporter, Volume 23, No. 1 (Fall 2017), 44-48

6 *Id.*

7 C. Villatoro, Medical Board of California sanctioned statement via electronic correspondence, dated August 26, 2019

8 https://www.medpagetoday.com/painmanagement/painmanagement/74856

9 Medical Board of California, Personal Correspondence, 2018

10 https://www.mbc.ca.gov/About_Us/Meetings/2019/ at 6:36-9:39

11 https://www.mbc.ca.gov/About_Us/Meetings/2019/ at 11:35-14:20

12 https://www.mbc.ca.gov/About_Us/Meetings/2019 / at 14:34-14:57

13 See fn. 1, supra

14 *Id.*

15 *Id.*

16 *Id.*

17 *Id.*

18 *Grafilo v. Cohanshohet* (2019) 32 Cal.App. 5th 428

19 *Id.*. at 435-36

20 *Id.* at 440

21 *Id.* at 437

22 *Grafilo v. Wolfsohn* (2019) 33 Cal.App.5th 1024

23 *Id.* at 1037

24 *Grafilo v Soorani* (Oct. 2, 2019, B286912) __ Cal.App.5th__, 2019 WL 5561411, publication ordered Oct. 29, 2019).

25 Bus. & Prof. Code, § 2241.5 (a)-(b)

26 The legislative history of this particular section is of note, "The Legislature finds and declares that, for the past 20 years, medical journals have reported that when physicians fail to manage their patients' pain appropriately it is partially out of fear of criminal prosecution." While this statute was drafted largely in response to criminal implications faced by providers, the same reasoning can easily be applied to ramifications see subsequent to implementation of the Project. While this section specifically denotes the Medical Board's continued jurisdiction and ability to take action if a physician's prescribing falls below the standard of care, the purpose of Business and Professions Code § 2241.5 was to specifically permit physicians to prescribe ongoing pain medications to patients commensurate with their intractable conditions, without fear of reprisal.

27 Bus. & Prof. Code, § 2241(a), (d)(2)

28 Health & Saf. Code, § 124960(J)

29 Health & Saf. Code, § 124961(d)

30 Health & Safety Code § 11165.4

31 https://www.sacbee.com/news/politics-government/capitol-alert/article199444229.html

32 https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf

33 https://www.mbc.ca.gov/