MEDICAL BOARD OF CALIFORNIA

Executive Director: Kimberly Kirchmeyer \diamond (916) 263–2389 \diamond License/Discipline Information: (916) 263–2382 \diamond Toll-Free Complaint Number: (800) MED-BDCA \diamond

Internet: <u>www.mbc.ca.gov</u>

Protection of the public shall be the highest priority for the Medical Board of California in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

— Business and Professions Code § 2000.1

he Medical Board of California (MBC) is a consumer protection agency within the state Department of Consumer Affairs (DCA). The 15-member Board consists of eight physicians and seven public members. MBC members are appointed by the Governor (who appoints all eight physicians and five public members), the Speaker of the Assembly (one public member), and the Senate Rules Committee (one public member). Members serve a four-year term and may be reappointed to a second term. The Board is assisted by several standing committees and ad hoc task forces.

The purposes of MBC are to protect consumers from incompetent, grossly negligent, unlicensed, impaired, or unethical practitioners; enforce the provisions of the Medical Practice Act, Business and Professions Code section 2000 *et seq.*; provide public-record information about physicians to the public via its website and individual requests; and educate healing arts licensees and the public on health quality issues. The Board's regulations are codified in Division 13, Title 16 of the California Code of Regulations (CCR).

MBC is responsible for ensuring that all physicians licensed in California have adequate medical education and training. In this regard, the Board issues regular and probationary licenses and certificates under its jurisdiction, administers a continuing medical education program, and administers physician and surgeon examinations to some license applicants. MBC also oversees the regulation of licensed midwives; polysomnographic technologists, technicians, and trainees; research psychoanalysts; and medical assistants.

In response to complaints from the public and reports from health care facilities and other mandated reporters, MBC reviews the quality of medical practice carried out by physicians and surgeons. In this regard, MBC's responsibilities include enforcement of the disciplinary, administrative, criminal, and civil provisions of the Medical Practice Act. MBC's enforcement staff receives and evaluates complaints and reports of misconduct and negligence against physicians. If there is reason to suspect a violation of the Medical Practice Act, an investigator from DCA's Health Quality Investigation Unit (HQIU), together with a deputy attorney general (DAG) from the Health Quality Enforcement Section (HQE) in the Attorney General's Office, will investigate the allegations and may file charges against alleged violators. Barring a stipulated settlement, the HQE DAG will prosecute the charges at an evidentiary hearing before an administrative law judge (ALJ) from the special Medical Quality Hearing Panel within the Office of Administrative Hearings (OAH). Following the hearing, a seven-member panel of MBC reviews the ALJ's proposed decision and takes final disciplinary action to revoke, suspend, or restrict the license, or impose other appropriate administrative action.

MBC meets approximately four times per year; its committees and task forces hold additional separate meetings as the need arises.

On July 26, 2017, Governor Brown reappointed Howard R. Krauss, M.D., and Ronald H. Lewis, M.D., to MBC for another term; both have served on the Board since 2013. Dr. Krauss has been director of neurosurgical ophthalmology at the Pacific Neuroscience Institute since 2014 and an ophthalmologist in private practice and clinical professor of ophthalmology and neurosurgery at the UCLA David Geffen School of Medicine since 1984. Dr. Lewis has been a physician at Ironwood State Prison since 2008. He was an urgent care physician at Eisenhower Immediate Care from 2003–2008, at Kaiser Permanent Urgent Adult Care Center in San Diego from 2003–2004, and at Sharp Rees-Stealy Medical Centers from 2001–2004. Dr. Lewis was an assistant Clinical Professor at the UC San Diego Department of Medicine from 2000–2016. Currently, MBC has two vacancies—one for a physician member and one for a public member.

On October 2, 2017, Christine Lally joined the Board as Deputy Director. Ms. Lally previously held the position of Deputy Director of Board and Bureau Relations at the Department of Consumer Affairs.

MAJOR PROJECTS

Sunset Review

On October 13, 2017, Governor Brown signed MBC's sunset extension bill, <u>SB</u> 798 (Hill) (Chapter 775, Statutes of 2017) (see LEGISLATION). However, passage of MBC's sunset extension bill stalled in the Assembly Business and Professions Committee in August due primarily to three controversial sections of the bill.

♦ Vertical Enforcement. Since 2006, Government Code section 12529.6 has required MBC, HQIU, and HQE to use "vertical enforcement" (VE) in most matters that survive initial screening by MBC's Central Complaint Unit (CCU) and are referred for formal investigation. Specifically, section 12529.6 requires: (1) such a matter to be jointly and simultaneously referred for handling by an HQIU investigator and an HQE deputy attorney general; (2) the investigation and prosecution (if any) are handled by that team for the life of the matter; and (3) the investigator is responsible for obtaining the necessary evidence under the direction of the DAG. VE requires investigators and the Attorney General to work collaboratively together from the beginning of a formal investigation, which is especially important when, as in quality of care cases, the legal and factual issues are complex.

VE was instituted in 2006 as a result of the passage of MBC's 2005 sunset bill, <u>SB</u> 231 (Figueroa) (Chapter 674, Statutes of 2005), and resulted from an extensive audit of MBC's enforcement program by the independent <u>Medical Board Enforcement Program Monitor</u>. The Monitor recommended not only the use of VE but also the transfer of MBC's investigators from the Board to HQE, so that the two sets of professionals could work at the same agency; the transfer proposal was rejected by the Schwarzenegger administration but the VE recommendation was included in SB 231. From its inception, VE has been controversial at MBC, whose staff has urged on several occasions that VE be limited to certain kinds of cases. However, the Board has not been receptive to limiting VE; during MBC's 2013 sunset review, when staff urged Board members to seek a change to section 12529.6 to limit VE to certain cases, Board members rejected that recommendation and directed the inclusion of the following statement in MBC's 2013 supplemental sunset

review report: "The Board believes that the benefits of VE are significant and does not believe that any legislative amendments need to be made to the Government Code sections of the VE statutes."

Similarly, in its <u>December 2016 sunset report</u> that became the subject of a public <u>hearing</u> on February 27, 2017, MBC barely discussed VE and did not call for its limitation to certain categories of cases (or for any change). However, at the February 27 hearing, Board President Dev GnanaDev, MD, stated:

The Board does believe that there should be discretion in terms of determining which cases should be investigated under the VE model. The Board has seen the benefits to specific case types being placed in the VE model. If specific case types are kept in the VE model and all other cases were investigated through the normal investigation process, this would enable the prosecutors to focus on the highest priority matters from the perspective of consumer protection. We believe there is value in using VE for these specific case types but not for all cases.

Despite the fact that MBC itself had never voted to repeal the VE statutes or confine VE to certain categories of cases, the April 18, 2017 version of SB 798 called for an outright repeal of Government Code section 12529.6. The <u>analysis</u> of the April 18 version of SB 798 explained some of the reasons for the proposed repeal: (1) "[t]here are still significant working relationship challenges between HQIU and HQE," (2) the fact that the law requires the DAG to "direct" investigations

no doubt impacts the team approach and may result in the expertise of both the investigator and DAG not being effectively utilized. Not every case should result solely in administrative action as initiated by a DAG, as investigations may bring criminal violations to light as well. HQIU faces an almost 40 percent vacancy in investigators, numbers that are not the same for other DOI investigators whose cases are not required to be coordinated with a DAG from the outset, and who may have independence in how they put their investigative skills to use.

and (3) "[a] March 2016 MBC report on VE showed that MBC has spent \$18.6 million to implement the program [since 2006] and provided statistical data showing that the average investigation timeframe has increased. In FY 2014/2015 the timeframe was 382 days and during FY 2015/2016 the timeframe increased to 426 days."

The Center for Public Interest Law (CPIL), whose Administrative Director Julianne D'Angelo Fellmeth served as MBC Enforcement Program Monitor from 2003-2005, opposed the repeal of VE. Throughout the spring of 2017, CPIL argued that the use of VE—despite MBC staff opposition and an investigator vacancy rate that ranged from 15-25% from 2006 through 2014—actually lowered MBC's average investigative timeframe by 30% from the 2006 inception of VE (from 354 days in 2008–2009 to 245 days in 2013– 14) until July 1, 2014, when MBC's investigators were removed from the Board and transferred to DCA's HQIU. In letters dated March 15 and April 19, 2017, CPIL argued that VE is not the cause of the soaring investigative timeframes; instead, the July 2014 transfer of MBC's investigators to HQIU—while well-intended—"has caused the investigator vacancy rate in HQIU to skyrocket and has had a devastating effect on the investigative case cycle time. The average shot up from 245 days in 2013–14 to 382 days in 2014–15 and then to 426 days in 2015–16." CPIL also noted that data from the first half of 2016–2017 indicate an average investigative case cycle time of 473 days, and again called for transfer of the investigators to HQE.

In letters dated <u>July 17</u> and <u>August 25</u>, 2017, the Attorney General's Office announced its opposition to SB 798 unless amended to eliminate the repeal of the VE statute. The Attorney General argued that

the current language in SB 798 is a serious step backwards to the days before the inception of the VE program when cases languished, and

substandard doctors continued to practice medicine. Before the VE program was implemented, the AGO prosecuted MBC cases based on a record of medical evidence compiled in isolation by MBC investigators through a 'hand off' model with little to no coordination with the AGO's HQE attorneys charged with prosecuting these cases.

Instead of repealing the VE statute, the Attorney General suggested a pilot program whereby HQE would hire investigators and medical consultants to work "under one roof,...in collaboration with AGO prosecutors, from start to finish, to prosecute complex MBC cases meriting quick intervention, such as in overprescribing, sexual abuse, repeat offenders, self-prescribing, and mental incapacity investigations."

At an August 29 hearing of the Assembly Business and Professions Committee, Senator Jerry Hill, author of SB 798, announced his decision to eliminate the repeal language and to substitute a sunset date on Government Code section 12526.9. The signed version of the bill places a January 1, 2019 sunset date on the VE statute, allowing the legislature to review the matter again during 2018.

◆ Exchange of Expert Witness Opinions Prior to Hearing. SB 231 (Figueroa), the 2005 bill that implemented many recommendations of the MBC Enforcement Program Monitor (see above), added section 2334 to the Business and Professions Code. That provision requires any party to a MBC disciplinary matter who wishes to introduce expert witness testimony at an evidentiary hearing to reduce that opinion to writing and exchange it with the other side at least 30 calendar days prior to commencement of the hearing. Section 2334 sets forth the contents of the expert opinion: (1) a curriculum vitae setting forth the qualifications of the expert, (2) a brief narrative statement of the general substance of the testimony that the expert is expected to give, "including any opinion testimony and its basis," (3) a representation that the expert has agreed to testify at the hearing, and (4)

the expert's hourly and daily fee for providing testimony and for consulting with the party who retained his/her services.

Although MBC did not call for any changes to section 2334 in its 2016 sunset report, SB 798 proposed to revise the provision to require the exchange of "a complete expert witness report," which must include the following: (1) a complete statement of all opinions the expert will express and the bases and reasons for each opinion, (2) the facts or data considered by the expert in forming the opinions, and (3) any exhibits that will be used to summarize or support the opinions. In addition, early versions of SB 798 required the exchange of the "complete expert witness report" 90 days prior to commencement of the hearing.

Both the California Medical Association (CMA) and the California Academy of Attorneys for Health Care Professionals, a group of attorneys who specialize in representing health care providers in disciplinary and civil malpractice matters, opposed the amendments to section 2334. Senator Hill agreed to reduce the exchange period back to 30 days, but the signed version of the bill contains the "complete expert witness report" requirements.

◆ Physician Disclosure of Probation Status to Patients. Early versions of SB 798 also included a provision requiring some physicians whose licenses are on probation to affirmatively disclose that fact to patients. This provision arose from two petitions by Consumers Union's Safe Patient Project (CUSPP) to MBC, both of which MBC rejected. CUSPP's proposal morphed from a requirement that all physicians on probation disclose that status to patients in a variety of methods, to a less onerous requirement applicable only to physicians whose licenses are on probation for egregious reasons (for example, sexual

misconduct and/or drug/alcohol addiction). CUSPP's petitions were strenuously opposed by CMA and MBC itself, which noted that it posts complete disciplinary decisions (including terms and conditions of probation) on its website.

For the last several years, Senator Hill has included a physician probation disclosure provision in several bills—most recently SB 798. As of the July 6 version of SB 798, proposed Business and Professions Code section 2228.1 would have required physicians whose licenses are on probation on and after July 1, 2018 for (1) sexual misconduct, (2) drug or alcohol abuse during practice, or (3) a criminal conviction involving the practice of medicine to affirmatively disclose their probationary status to patients. Additionally, physicians who have previously surrendered their license, had their license revoked, or have been ordered to be on probation for a violation constituting a threat to public health and safety, and physicians found to have committed (or stipulated to) any violation constituting a threat to public safety where the Board believes notification is appropriate would also have had to affirmatively disclose their probation to patients. Both CMA and MBC continued to oppose the proposal. When the Assembly Business and Professions Committee asked Senator Hill to amend SB 798 to require even fewer physicians to disclose their probation, Senator Hill withdrew the provision entirely.

Once these and other contentious issues were resolved, the sunset extension bill was passed by the legislature and signed by the Governor. However, Governor Brown included a "signing message" which states:

Two issues were identified during the legislative process requiring further review: vertical enforcement and the exchange of expert witness reports between a doctor under investigation and the Medical Board. I am directing my staff to work with the Legislature and the Attorney General's Office to determine what changes are needed.

HQIU Vacancy Rate—and Investigative Timeframes—Sky High

At MBC's April and July 2017 meetings, HQIU Chief David Chriss and Deputy Chief Kathleen Nicholls reported on the vacancy rate for HQIU investigators (see above) and steps that the Unit is taking to fill those vacancies. As of the April meeting, 31 (or 40%) of HQIU's investigation positions were vacant (although candidates for 21 of those vacancies had been identified and were undergoing background checks), and it took HQIU an average of 492 days (1.35 years) to complete the investigative phase of the long disciplinary process. As of the July meeting, 29 positions (38%) were vacant and it took HQIU an average of 467 days (1.28 years) to complete an investigation.

This is not a new problem at MBC. In fact, according to the *Initial Report of the Medical Board Enforcement Monitor*, MBC has suffered from an inability to recruit and retain experienced investigators for decades, largely because the salary scale for MBC/DCA investigators lags behind salaries of similar peace officer investigators employed by the Attorney General's Office and other state agencies, including the Department of Insurance and the Department of Alcoholic Beverage Control. As far back as 1990, the legislature recognized this problem and inserted intent language into SB 2375 (Presley) (Chapter 1597, Statutes of 1990) stating: "It is ... the intent of the Legislature that the pay scales for investigators of the Medical Board of California be equivalent to the pay scales for special investigative agents of the Department of Justice, in order to attract and retain experienced investigators." Despite decades of effort by MBC staff, such parity has never occurred.

At the April meeting, Deputy Chief Nicholls reported on the latest such effort. She

noted that MBC and DCA had submitted a proposal for investigator retention pay to the state's personnel agencies for review. Two of those agencies agreed to award a 7.44% pay increase to all DCA investigators (not simply HQIU investigators, whose cases are generally more complex than those of other DCA investigators) who are and have topped out of their salary range for at least twelve months. This increase, if approved by the legislature, would address only rank and file investigators and not investigative supervisors and managers. However, Ms. Nicholls stated that the increase, if approved, would assist in attracting qualified candidates with prior investigative experience. She also reported that HQIU had hired 15 non-sworn investigators who are assisting with MBC cases; seven of these individuals are undergoing background checks for future employment with HQIU.

At the Board's July meeting, Chief Chriss reported that the 7.44% recruitment and retention pay differential for DCA investigators was approved by the legislature and became effective on July 1, 2017. Again, this pay differential is awarded only to investigators who have been at the top step of their salary range for twelve months or more. He also announced that HQIU would be hiring a number of limited-term special investigators and several retired annuitant special investigators to help sworn investigators with their high MBC caseloads and to handle unlicensed practice cases not involving patient harm.

Detection of Overprescribing Physicians: CURES 2.0, MBC, and DPH

At the July 2017 meeting of MBC's Enforcement Committee, Executive Director Kim Kirchmeyer reported on a new approach to identifying physicians who may be overprescribing controlled substances.

According to the Centers for Disease Control and Prevention (CDC), drug overdose deaths and opioid-involved deaths are the leading cause of accidental death in the United States. From 2000 to 2015, more than one-half million people died from drug overdoses. The majority of drug overdose deaths (more than six out of ten) involve an opioid. Deaths from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—have more than quadrupled since 1999.

MBC has traditionally relied on consumer complaints to alert it to physician misconduct, including overprescribing. However, patients who are seeking painkillers and other addictive narcotics are not likely to file a complaint with MBC; instead, these patients are often actively "doctor-shopping" to obtain multiple narcotics prescriptions from multiple prescribers, and even "pharmacy-shopping" to get those prescriptions filled at a variety of different pharmacies in hopes of avoiding detection.

In investigating cases of possible overprescribing, MBC and other law enforcement agencies have—since 1998—been able to rely on the Controlled Substance Utilization Review and Evaluation System (CURES) maintained by the Department of Justice (DOJ). CURES is California's "prescription drug monitoring program" (PDMP), an electronic repository of the prescription and dispensation of all Schedule II, III, and IV narcotics in California, and is intended to enable MBC and other law enforcement agencies to detect prescribers (including physicians) and dispensers (including pharmacists) who are prescribing and dispensing dangerously addictive controlled substances to patients who may be "doctor-shopping" and/or "pharmacy-shopping" in order to acquire excessive amounts of controlled substances for their own misuse, abuse, unlawful sale, or other distribution. Under Health and Safety Code section 11165, dispensing pharmacies and

clinics must provide specified prescription data for each prescription for a Schedule II, III, or IV controlled substance to DOJ on a weekly basis. Beginning in 2009, DOJ converted CURES to a searchable database that registered prescribers and dispensers could access in order to determine whether a patient is drug-seeking from multiple prescribers and pharmacies. However, CURES soon became a victim of the state's general fund fiscal crisis in 2011 and had to be rescued by the legislature.

SB 809 (DeSaulnier) (Chapter 400, Statutes of 2013) imposed a small surcharge on the licensing fees of most prescribers of controlled substances in order to create a stable funding mechanism necessary to enable DOJ to update and maintain CURES. On December 22, 2015, DOJ announced the launch of the revamped and more user-friendly "CURES 2.0," and subsequent legislation—AB 679 (Allen) (Chapter 778, Statutes of 2015)—required all prescribers to register with CURES by July 1, 2016. Recent legislation—SB 482 (Lara) (Chapter 708, Statutes of 2016)—added new section 11165.4 to the Health and Safety Code, which requires all prescribers (with fairly significant exceptions) to consult CURES before issuing Schedule II, III, or IV controlled substances to a patient for the first time (and at least once every four months thereafter if the substance remains part of the treatment of the patient). The CURES consultation requirement does not become effective until six months after DOJ certifies that the CURES database is ready for statewide use and that the Department has adequate staff to maintain it. That certification has not yet occurred.

In the meantime, the legislature sought to ensure that MBC receives information about prescription drug overdose deaths in a different manner. Existing Business and Professions Code section 802.5 requires coroners who receive information indicating that

a death may be the result of physician gross negligence or incompetence to file a report with MBC. Even though thousands of Californians have died due to prescription drug overdose, MBC receives an average of only five coroners' reports per year—indicating that coroners do not consider a prescription drug overdose death to be the result of either gross negligence or incompetence. In 2013, SB 62 (Lieu) sought to augment section 802.5 by additionally requiring coroners to file a report with MBC when they receive information indicating that a death was caused by a Schedule II, III, or IV drug. During legislative debate on SB 62, the appropriations committees estimated that the bill would result in "absorbable" costs to coroners' offices. Specifically, the Senate Appropriations Committee opined that "[a]ssuming that local coroners spend about one to two hours preparing materials for each report to the Medical Board, the statewide annual costs to reimburse the coroners for their costs will likely be between \$150,000 and \$350,000 per year." Similarly, the Assembly Appropriations Committee estimated "[p]otential state-reimbursable mandate costs in the range of \$100,000 [general fund] annually to county coroner's offices for new required reports." However, CMA opposed the bill and Governor Brown vetoed it, stating: "While I am concerned about the harm caused by prescription drug misuse and overdose, the bill creates an unfunded mandate for the state, potentially in the millions of dollars."

Thus, at the July 2017 Enforcement Committee meeting, Executive Director Kirchmeyer reported that MBC staff—following the veto of SB 62—consulted with the Senate Committee on Business, Professions and Economic Development and then contacted the Department of Public Health (DPH), which is responsible for collecting all death certification information. After several months of meetings, MBC signed an

interagency agreement with DPH to obtain information on deaths in 2012 and 2013 related to opioid prescription drugs; in August 2015, MBC received that information. Once MBC received the data file, it used CURES to determine the identity of each deceased's prescriber and also looked at the prescribing practices of the attending physician, or the physician who certified the death. Once MBC received the CURES information, it asked experts to review the data to determine if there might have been inappropriate prescribing. Ms. Kirchmeyer stated that all of the reports had been reviewed and that MBC was working to initiate all appropriate cases by sending them to CCU so it can obtain medical records, or by sending them directly to the field for investigation.

During the two years for which MBC has data, prescription drugs were identified as an underlying cause of death or a contributing cause of death of 2,692 patients. Of those, 2,256 prescribing physicians had a CURES report that needed review by an expert medical reviewer. After those reviews, MBC identified 522 cases that needed an investigation opened concerning a physician who may have inappropriately prescribed, and MBC is writing letters requesting authorization to obtain and review medical records of the deceased patients.

Kirchmeyer noted that although this project is time- and resource-consuming, the experts who have reviewed these cases have provided excellent feedback and they believe the project is worth the effort because it gives MBC a chance to discover the identities of overprescribers without having to wait for specific complaints (which may never be forthcoming). These experts advised MBC to continue to obtain this information from DPH every year, which MBC intends to do.

Disciplinary Demographics Task Force

At MBC's April and July 2017 meetings, the Disciplinary Demographics Task Force, consisting of physician member Howard Krauss, MD, and public member Jamie Wright, Esq., reported the Task Force's activities to the full Board.

The Task Force was created in January 2017 with the release by the California Research Bureau (CRB) of a report entitled *Demographics of Disciplinary Action by the Medical Board of California* (2003–2013). MBC commissioned the CRB report after receiving complaints from members of the African-American physician community and a formal request from the Golden State Medical Association (GSMA) which complained over the course of multiple meetings that African-American physicians were being targeted or "profiled" by MBC's enforcement program, and have been disproportionately disciplined by MBC in relation their population within the overall physician community and in comparison to other ethnic groups.

CRB released its report in January 2017. Using archival data provided by MBC of complaints, investigations, and discipline that occurred from July 2003 through June 2013, CRB determined that there is a correlation between physician race and the pattern of complaints, investigations, and discipline. Latino and African-American physicians were both more likely to be the subject of complaints and more likely to see those complaints escalate to investigations. According to the study, Latino physicians were also more likely to see those investigations result in disciplinary outcomes. CRB noted that its findings "should be taken with the caveat that this is an observational study, and many variables affecting the perception of physician performance (for instance, 'bedside manner') could not be taken into account." CRB further determined that while there is evidence of disparate

outcomes, there is no evidence that any actor has specifically applied racial bias to achieve these outcomes.

Despite the limitations of the CRB study, MBC members and staff announced that they are taking the disparities identified in the report seriously and plan to take proactive steps to investigate and address them. Thus, MBC created the Task Force, which is researching training on implicit bias; this training will be provided to all individuals involved in MBC's enforcement process, from Board staff and members to investigators, medical consultants, expert witnesses, prosecutors, and ALJs (if not already required). At the April meeting, Dr. Krauss noted that implicit bias training is already provided to other entities; however, that training will be scrutinized by MBC staff to ensure it includes everything the Board wants to cover. MBC anticipates contracting with a vendor that can provide both in-person training and webinar interactive training that can be completed online for Board members and expert reviewers; the expectation is that the training will be repeated every two years.

At the Board's July meeting, Ms. Wright reported that staff had found a vendor to provide the implicit bias training to anyone who may be involved in MBC's investigative or disciplinary processes; the training sessions are expected to begin during the fall of 2017. She also noted that she and Dr. Krauss had met with GSMA representatives to discuss other responses to the CRB report, including the possible redaction of certain information from the complaint, investigation, and prosecution process; this information might include the licensee's medical school and location where postgraduate training took place, as this information might inject unconscious bias into the process and it is irrelevant to the action

to be taken by the Board. Staff intends to consult HQIU and HQE on this matter before drafting a written policy.

At both Board meetings, GSMA representatives thanked MBC members and staff for their attention to this matter and expressed hope that their efforts would decrease any discriminatory effect in the process so that Californians are not deprived of quality practicing physicians due to any type of bias, whether conscious or unconscious.

Physician Health and Wellness Program

On October 4, 2017, MBC held a second "interested parties meeting" on draft regulations to implement <u>SB 1177 (Galgiani) (Chapter 591, Statutes of 2016)</u>; the October meeting followed a similar January 11, 2017 meeting.

Sponsored by CMA, SB 1177 authorizes the Board to create and establish a "physician and surgeon health and wellness program" (PHP) to provide early identification of, and appropriate interventions to support, a physician in his/her rehabilitation from substance abuse to ensure that the licensee remains able to practice medicine in a manner that will not endanger the public health and safety while maintaining the integrity of the medical profession.

From 1981 through 2008, MBC had a physician "Diversion Program" that was supposed to monitor the behavior of substance-abusing physicians through several "monitoring mechanisms" such as random drug testing, meeting attendance at group meetings of other health care providers in recovery, required worksite monitors, and psychotherapy. That program was run in-house by approximately ten MBC employees who were assisted by dozens of paid contractors across the state who, for example, collected urine samples from participants and sent them to a laboratory for testing, and conducted

group therapy meetings for participants. For 24 years of its 27-year history, MBC's Diversion Program was overseen not by MBC or an MBC committee, but by a "Liaison Committee to the Diversion Program" consisting of representatives of CMA, the California Society of Addiction Medicine, and the California Psychiatric Association.

The prior program was audited five times during its 27-year history; it failed all five audits, including a 2004 audit by the independent Medical Board Enforcement Monitor. As a result of that audit, the legislature passed SB 231 (Figueroa) (Chapter 674, Statutes of 2005), which placed a 2008 sunset date on the statutes creating the diversion program, and expressed the legislature's intent that

the Bureau of State Audits conduct a thorough performance audit of the diversion program of the Medical Board of California to evaluate the effectiveness and efficiency of the program, and make recommendations regarding the continuation of the program and any changes or reforms required to assure that physicians and surgeons participating in the program are appropriately monitored, and the public is protected from physicians and surgeons who are impaired due to alcohol or drug abuse or mental or physical illness. The audit shall be completed by June 30, 2007.

BSA issued its <u>audit</u> on June 7, 2007—which became the program's fifth failed audit. On July 27, 2007, MBC voted unanimously to let the June 30, 2008 sunset date pass, and the program ended on that date.

Since then, CMA and other physician organizations have repeatedly attempted to re-create another program for substance-abusing physicians. Also, since then, the legislature passed SB 1441 (Ridley-Thomas) (Chapter 548, Statutes of 2008), which required DCA to convene a "Substance Abuse Coordination Committee" (SACC) to develop "uniform and specific standards in [sixteen specified areas] that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program." Although the SACC finalized the <u>Uniform Standards</u>

Regarding Substance-Abusing Healing Art Licensees ("Uniform Standards") in April 2011, none of CMA's bills agreed to abide by them—until SB 1177 (Galgiani).

SB 1177 authorizes MBC to create a PHP and requires it to be administered not by Board staff but by an outside entity selected through a competitive bidding process. The statute permits only physicians who have voluntarily self-referred into the program and physicians who are required to participate in it as a condition of probation to participate in it. SB 1177 expressly requires the program to comply with the Uniform Standards, and the contract between the Board and the outside entity must require the entity to provide MBC with detailed data and statistics sufficient to enable the Board to meaningfully oversee the program; further, and consistent with the Uniform Standards, the program must submit to periodic audits and inspections. The SB 1177 program also differs from MBC's prior program in that the Diversion Program was cross-subsidized by licensing fees paid by all physicians; SB 1177 requires program participants to pay a fee that will be set by the Board, and the statute requires the Board to set the fee "at a level sufficient to cover all costs for participating in the program, including any administrative costs incurred by the board to administer the program."

At the October interested parties meeting, Board staff previewed draft regulations for the PHP and accepted public comment on each provision. Board legal counsel Kerrie Webb also noted that with the passage of SB 796 (Hill) (see LEGISLATION), Uniform Standard #4 regarding drug testing may be revised by the SACC. However, MBC plans to initiate the rulemaking process as soon as possible, and to revise Uniform Standard #4 (if necessary) during that process if possible.

At this writing, MBC plans to review the draft regulations at its October 27 meeting;

thereafter, they must be reviewed by a number of control agencies before MBC may publish them for a 45-day public comment period.

MBC Rulemaking

The following is a description of recent rulemaking proceedings undertaken by the Medical Board:

◆ Midwife Assistant Training and Certification Regulations. On September 21, 2017, the Office of Administrative Law (OAL) approved MBC's adoption of new Article 6 of Chapter 3 (sections 1379.01, 1379.02, 1379.03, 1379.04, 1379.05, 1379.06, 1379.07, 1379.08, and 1379.09), Title 16 of the CCR, to implement SB 408 (Morrell) (Chapter 280, Statutes of 2015). MBC originally published notice of its intent to adopt these regulations in the California Regulatory Notice Register on June 3, 2016.

Specifically, new section 1379.01 authorizes licensed midwives (LMs) and certified nurse-midwives (CNMs) to supervise midwife assistants but specifies that the supervising LM or CNM is responsible for the patient's treatment and care. New sections 1379.02–04 require all midwife assistants to receive specified training, including Neonatal Resuscitation Certification from the American Academy of Pediatrics (1379.02), certification in basic life support from the American Heart Association or the American Safety and Health Institute (1379.03), and training in CDC's "Guidelines for Infection Control in Health Care Personnel" (1379.04). New section 1379.05 specifies minimum training requirements for all midwife assistants and sets forth additional training requirements for midwife assistants who are permitted to engage in specialized procedures. New section 1379.06 specifies that the required training may be administered under the supervision of a LM or CNM, or in specified educational programs authorized by the

Department of Education or the Bureau for Private Postsecondary Education. New section 1379.07 specifies the minimum requirements that a certifying organization for midwife assistant training must meet in order to receive Board approval, while new section 1379.08 sets forth changes that Board-approved certifying organizations must report to the Board and the timeframes within which the organization must report such changes to the Board. New section 1379.09 specifies processing times within which the Board must review an application from a certifying organization.

These regulations became effective on September 21, 2017.

- ♦ Physicians on Probation. On October 10, 2017, OAL approved MBC's amendment of section 1358, Title 16 of the CCR. Amended section 1358 requires physicians placed on probation by the Board to be subject to the Board's Probation Program and to fully cooperate with representatives of the Board and its personnel. Cooperation includes, but is not limited to, compliance with each term and condition in the order placing the physician on probation, and submission to biological fluid testing for the purpose of determining the existence of alcohol, narcotics, other controlled substances and/or dangerous drugs in the physician's system. The biological fluid tests must be made at the times and places required by the Board or its authorized representative. Additionally, any monetary fees incurred as a result of a term or condition of probation, or biological fluid testing, are to be paid by the physician on probation. The Board originally noticed its proposed amendments in September 2016. This regulatory change becomes effective on January 1, 2018.
- ◆ Citations and Fines for Allied Health Professionals. At this writing, the rulemaking file on proposed regulatory changes authorizing MBC to impose citations and

fines on allied health professionals regulated by MBC is pending at OAL. According to the statement of reasons, MBC proposes to amend sections 1364.10, 1364.11, 1364.13, and 1364.15, Title 16 of the CCR, to add licensed midwives and polysomnographic technologists, technicians, and trainees as licensees/registrants to whom the Board may issue citations with orders of abatement and fines when these allied health care professionals violate statutes or regulations referenced in section 1364.11. The Board originally noticed its proposed amendments in September 2016.

LEGISLATION

SB 798 (Hill), as amended September 8, 2017, is MBC's sunset extension bill; it amends Business and Professions Code sections 2001 and 2020 to extend, until January 1, 2022, the existence of MBC and its authority to hire an executive director, respectively. Additionally, the bill makes a number of significant changes in a variety of areas:

◆ *Licensing Program*. The bill makes a number of changes to the Board's licensing program requested by MBC during its sunset review. The bill repeals section 2420 and amends section 2423 to permit MBC to issue a two-year license (instead of issuing licenses that expire at the end of the licensee's birth month, which sometimes results in licensees overpaying for their license).

SB 798 significantly changes MBC's postgraduate training (PGT) requirement for licensure. Under current sections 2065 and 2066, an applicant must complete one or two years of an approved PGT program (depending on where the applicant attended medical school) in order to become licensed as a physician in California. SB 798 amends both of these sections (and makes conforming changes to other provisions) and adds new section

2096, which requires all applicants—effective January 1, 2020 and regardless of school of graduation—to complete a minimum of three years of approved PGT prior to the issuance of a full unrestricted license to practice. The bill also adds section 2064.5, which—effective January 1, 2020—creates a new "postgraduate training license" that medical school graduates must obtain from MBC within 180 days after enrollment in an approved PGT program. New section 2064.7 sets forth grounds for denial of a PGT license, and new section 2064.8 permits MBC to issue a PGT license to a graduate who has committed minor violations of unprofessional conduct provided certain conditions are met (and which may be accompanied by a public letter of reprimand).

In a related change, the bill—effective January 1, 2020—repeals sections 2089 and 2089.5; these sections set forth detailed medical school curriculum requirements that must be met by United States and international medical schools in order for their graduates to be deemed approved for licensure in California. These changes also repeal section 1314.1, Title 16 of the CCR, which sets forth costly and resource-consuming requirements for MBC's international medical school recognition process; this process requires MBC to evaluate and assess medical education from international medical schools throughout the world. Instead, new section 2084 allows MBC to rely on lists of approved medical schools in the World Directory of Medical Schools and/or that are prepared by other recognized accreditors of medical school education.

◆ *Use of the Term "Board-Certified.*" SB 798 also amends Business and Professions Code section 651, which currently prohibits physicians from using the term "board-certified" unless the specialty board which has certified them is (1) one of the 24 specialty boards which are members of the American Board of Medical Specialties; or (2)

a board or association with an Accreditation Council for Graduate Medical Education-approved PGT program that provides complete training in that specialty or subspecialty; or (3) a board or association with "equivalent requirements" approved by MBC. SB 798 limits MBC's ability to approve specialty boards for purposes of the use of the term "board-certified" in California by eliminating the third option in section 651 concerning MBC approval of "equivalent requirements."

♦ Enforcement Program. SB 798 also makes changes in MBC's enforcement program. Prior versions of the bill would have completely repealed the "vertical enforcement" (VE) model of investigating and prosecuting physician discipline matters mandated in 2006 in Government Code section 12529.6 (see MAJOR PROJECTS). The enacted version of SB 798 preserves the VE mandate but imposes a January 1, 2019 sunset date on section 12529.6.

Also, in the enforcement area, the bill amends Business and Professions Code section 2232, which currently requires MBC to "promptly" revoke the license of any physician who has been convicted of a crime requiring sex offender registration pursuant to Penal Code section 290. SB 798 amends section 2232 to require (with some exceptions) automatic revocation of the license of a physician who has been required to register as a sex offender, regardless of whether that conviction has been appealed. A physician whose license has been automatically revoked pursuant to this section may request a hearing within 30 days of the revocation; that hearing must be conducted pursuant to the Administrative Procedure Act.

Enacted in 2010, Business and Professions Code section 805.01 requires hospitals and their peer review bodies to file a report with MBC within 15 days after a peer review

body makes a final decision or recommendation regarding action proposed to be taken against a physician's admitting privileges based on the peer review body's determination that one of several specified acts may have occurred, regardless of whether hearings pursuant to Business and Professions Code section 809.2 have been requested or have been held. The specified acts include: (1) incompetence or gross or repeated deviation from the standard of care involving death or serious bodily injury to one or more patients; (2) the use of, or prescribing for or administering to himself or herself, any controlled substance; or the use of any dangerous drug or alcohol to the extent or in such a manner as to be dangerous to the physician, any other person, or the public, or to the extent that the use impairs the physician's ability to practice safely; (3) repeated acts of clearly excessive prescribing or controlled substances, or doing so without a good fair prior examination of the patient and a medical reason therefor; and (4) sexual misconduct with one or more patients during a course of treatment or examination. Although the purpose of section 805.01 reports is to provide the Board with early information about these serious charges so MBC may investigate and take appropriate action to further consumer protection at the earliest possible moment, MBC has received very few of these reports since section 805.01 became effective. SB 798 encourages compliance, and deters noncompliance, with section 805.01 by authorizing MBC to impose a \$100,000 fine on hospitals that intentionally fail to file a section 805.01 report when required to do so; and a \$50,000 fine on other failures to file a section 805.01 report.

Also in the enforcement area, Business and Professions Code section 2334 currently requires any party to a MBC disciplinary matter that seeks to introduce expert medical testimony to exchange, within 30 days of the commencement of an evidentiary

hearing in that matter, the curriculum vitae and a "brief narrative statement of the general substance of the testimony that the expert is expected to give, including any opinion testimony and its basis" (see MAJOR PROJECTS). SB 798 amends section 2334 to require any party seeking to introduce expert medical testimony to exchange "a complete expert witness report," which must include "[a] complete statement of all opinions the expert will express and the bases and reasons for each opinion"; "[t]he facts or data considered by the expert in forming the opinions"; and "[a]ny exhibits that will be used to summarize or support the opinions."

Government Code section 11529 permits an ALJ from the Office of Administrative Hearings to issue an "interim suspension order" (ISO) restricting or suspending the license of a physician pending conclusion of the disciplinary process. If an ALJ issues an ISO, the Attorney General's Office must file a formal accusation in the matter within 30 days of the issuance of the ISO. The existing section does not recognize that, in some cases, it is more appropriate for the AG to file a petition to revoke probation; thus, SB 798 amends section 11529 to require the AG to file an accusation or petition to revoke probation within 30 days of the issuance of an ISO.

By regulation, MBC currently requires all licensees to disclose to patients the fact that they are licensed by MBC; that disclosure must include MBC's toll-free number and website address. In response to complaints by consumer groups that these disclosures are inadequate, SB 798 adds new section 2026 to the Business and Professions Code; that section requires MBC to initiate the rulemaking process prior to January 1, 2019, to require its licensees and registrants to provide notice to their patients or clients that the practitioner is licenseed by the Board, that the practitioner's license can be checked, and that complaints

against the practitioner can be made through the Board's website or by contacting the Board.

• Other Changes. The bill also makes a number of miscellaneous changes to multiple provisions: (1) it clarifies that the Board of Podiatric Medicine (BPM) is no longer part of MBC and that BPM (not MBC) issues licenses to doctors of podiatric medicine (DPMs); (2) it expressly refers to BPM in many statutory provisions; (3) it adds DPMs to the definition of "attending physician" in Health and Safety Code section 11362.7, thus allowing DPMs to recommend marijuana for medical purposes; (4) it adds licensed midwives to statutes governing peer review reporting; (5) it amends Health and Safety Code section 128335 to permit MBC to appoint two members to the board of the Health Professions Education Foundation, which administers MBC's loan repayment assistance program to enhance access to medical care in underserved communities; (6) it repeals a provision in Business and Professions Code section 2008 that prohibits the Board President from serving on a disciplinary panel "unless there is a vacancy in the membership of the board"; and (7) it amends Business and Professions Code section 2216.3 to substantially clarify the "adverse events" that outpatient surgical settings accredited pursuant to Health and Safety Code section 1248.1 must report to MBC no later than five days after the adverse event has been detected.

Governor Brown signed SB 798 on October 13 (Chapter 775, Statutes of 2017). In a "signing message" accompanying his signature, the Governor stated:

Two issues were identified during the legislative process requiring further review: vertical enforcement and the exchange of expert witness reports between a doctor under investigation and the Medical Board. I am directing my staff to work with the Legislature and the Attorney General's Office to determine what changes are needed.

AB 40 (Santiago), as amended on September 8, 2017, is an urgency bill that amends section 11165.1 of the Health and Safety Code to require DOJ to make electronic prescription records contained in its CURES system accessible through integration with a health information technology system beginning October 1, 2018, if that system meets certain information security and patient privacy records. Thus, the bill will allow an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist to access the CURES database through an authorized health information technology system beginning no later than October 1, 2018. According to the author,

California's prescription drug monitoring program, CURES, is a critical tool that helps combat prescription drug abuse. AB 40 integrates CURES with emergency room health information technology systems. This will allow prescription information to be included in the same patient information that emergency physicians already receive. AB 40 will help reduce stress on California's overcrowded emergency departments by allowing emergency physicians to more efficiently receive information and helps fight prescription drug abuse.

Governor Brown signed AB 40 on October 9, 2017 (Chapter 607, Statutes of 2017).

AB 443 (Salas), as amended on September 8, 2017, amends section 3041 of the Business and Professions Code to expand the scope of practice of optometrists. It also amends section 3041.1 to require that an optometrist consult with and, if necessary, refer a patient to a physician and surgeon or other appropriate health care provider when a situation or condition occurs that is beyond the optometrist's scope of practice. AB 443 further amends section 3041.1 to require optometrists to document consultations, referrals, and notifications in the patient record. MBC opposed AB 443, stating:

This bill expands the scope of an optometrist, but in most cases does not require any additional training, education, or collaboration with a physician. Allowing optometrists to perform these additional procedures, diagnose and

treat more conditions and prescribe additional topical or oral therapeutic pharmaceutical agents may result in consumer harm if the optometrist does not have the proper training, education and physician collaboration.

Governor Brown signed AB 443 on October 7, 2017 (Chapter 549, Statutes of 2017).

AB 715 (Wood), as amended September 13, 2017, would have added sections 1179.90–1179.92 to the Health and Safety Code to require the state Department of Public Health to convene a workgroup to develop a statewide guideline for prescribing opioids for acute, short-term pain; and to submit to the legislature a report of the workgroup's conclusions and recommendations on or before March 1, 2019. Specifically, AB 715 would have required the workgroup to review existing prescription guidelines, including guidelines developed by CDC and MBC; and develop a recommended statewide guideline addressing best practices for prescribing opioid pain relievers for instances of acute, short-term pain, including the appropriateness of limiting initial prescription duration and the appropriateness of a differing prescribing protocol for individuals under 21 years of age and pregnant or lactating women.

Governor Brown <u>vetoed</u> AB 715 on October 9. In his veto message, he stated the bill is unnecessary because

[s]ince 2014, the Department of Public Health has led the Prescription Opioid Misuse and Overdose Prevention Workgroup which is comprised of state and local agencies as well as medical and patient organizations committed to reducing opioid overdose rates in California. Furthermore, both the California Medical Board and the federal Centers for Disease Control have published updated guidelines for prescribing controlled substances for pain including opioids.

AB 1048 (Arambula), as amended on September 8, 2017, and as it pertains to MBC, adds section 4052.10 to the Business and Professions Code, to authorize a pharmacist to dispense opioids as a partial fill if requested by the prescribing physician or

patient; and amends Health and Safety Code section 1105 to remove the requirement that pain be assessed at the same time as vital signs. The bill defines a "partial fill" as a part of a prescription filled that is of a quantity less than the entire prescription." According to the California Medical Association (the bill's sponsor),

[o]pioid addiction and overdosing is a multi-faceted issue that is growing in the United States and in California specifically. With over 2,000 opioid overdose deaths in California in 2014 alone, there are steps that California Legislature can take to prevent the over prescription of opioids and minimize the number of pills available for unintentional or intentional diversion.

Governor Brown signed AB 1048 on October 9, 2017 (Chapter 615, Statutes of 2017).

AB 1340 (Maienschein), as amended August 30, 2017, adds section 2191.5 to the Business and Professions Code, which requires MBC to consider including in its continuing medical education requirements a course in integrating mental and physical health care in primary care settings, especially as it pertains to early identification of mental health issues and exposure to trauma in children and young adults and their appropriate care and treatment. Governor Brown signed AB 1340 on October 13, 2017 (Chapter 759, Statutes of 2017).

SB 241 (Monning), as amended September 7, 2017, amends Health and Safety Code section 123110 regarding access to medical records. The bill conforms California's Patient Access to Health records law governing the right of patients to access and copy their medical records to the federal Health Information Portability and Accountability Act of 1996 (HIPAA), including requiring health care providers to provide the records in an electronic format if they are maintained electronically and if the patient requests the records in an electronic format; more clearly specifying the reasonable clerical costs that may be charged by the providers; and by making other technical, clarifying and conforming

changes. Governor Brown signed SB 241 on October 5, 2017 (Chapter 513, Statutes of 2017).

SB 512 (Hernandez), as amended on August 21, 2017, adds Business and Professions Code section 684 regarding health care practitioners' use of stem cell therapy. SB 512 defines "stem cell therapy" as a therapy involving the use of human cells, tissues, or cellular or tissue-based products, pursuant to section 1271.3 of Title 21 of the Code of Federal Regulations. SB 512 requires health care practitioners who perform stem cell therapy that is not approved by the U.S. Food and Drug Administration to communicate to a patient seeking stem cell therapy the following information in English:

THIS NOTICE MUST BE PROVIDED TO YOU UNDER CALIFORNIA LAW. This health care practitioner performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care physician prior to undergoing a stem cell therapy.

The information must be communicated in a prominent display in an area visible to patients in the health care practitioner's office and posted conspicuously in the entrance of the health care practitioner's office and in a written document prior to providing the initial stem cell therapy. MBC is prohibited from taking disciplinary action for a first violation of this disclosure requirement; however, after a first violation, MBC may issue a citation and fine the health care practitioner a maximum of \$1,000 per violation. Further, the Board must include in its annual report the following information with regard to licensees who perform stem cell therapies: number of complaints received, any disciplinary actions taken, and any administrative actions taken. Governor Brown signed SB 512 on October 2, 2017 (Chapter 428, Statutes of 2017).

SB 554 (Stone), as amended June 14, 2017, adds sections 2836.4 and 3502.1.5 to the Business and Professions Code to allow a nurse practitioner (NP) or a physician assistant (PA) to furnish or order buprenorphine when done in compliance with the provisions of the Comprehensive Addiction and Recovery Act of 2016; prior to doing so, an NP or a PA must complete at least 24 hours of initial training by an approved training entity. According to the author's office,

Many NPs and PAs may not be aware of the process needed to gain the authority to prescribe buprenorphine to treat opioid addiction. Opioid addiction is a growing problem that must be medically addressed during recovery. The more professionals that have the ability to treat this addiction the better we can bring access to those in need.

MBC supported this bill, which Governor Brown signed on September 11, 2017 (Chapter 242, Statutes of 2017).

SB 796 (Hill), as amended September 5, 2017, as it pertains to MBC, amends section 315 of the Business and Professions Code to require DCA's Substance Abuse Coordination Committee—which has been tasked with developing uniform and specific standards that all DCA health care boards must use in disciplinary matters involving substance-abusing licensees (see MAJOR PROJECTS)—to review the existing criteria in Uniform Standard #4, which establishes substance abuse testing standards and schedules, by January 1, 2019. The goal in reviewing Uniform Standard #4 is to determine whether its existing drug testing criteria should be updated to reflect recent developments in testing research and technology. Governor Brown signed SB 796 on October 8, 2017 (Chapter 600, Statutes of 2017).

LITIGATION

In *Lewis v. Superior Court*, 3 Cal. 5th 561 (July 17, 2017), the California Supreme Court rejected a physician's argument that MBC must secure a search warrant or subpoena or make a showing of good cause before accessing the CURES prescribing records of a physician who is the subject of a complaint, and held that MBC did not violate the physician's patients' right to privacy under article I, section 1 of the California Constitution by accessing the physician's prescribing history from CURES (see MAJOR PROJECTS).

In November 2008, MBC initiated an investigation of licensee Alwin Carl Lewis after a patient filed a complaint with the Board. The patient complained that Dr. Lewis advised her to go on a stringent diet. An MBC investigator obtained a CURES prescriber activity report on Dr. Lewis; it was 205 pages long and contained the prescription information of hundreds of patients. After reviewing the report, the Board asked five of Dr. Lewis's patients for release of their full medical records. Three patients gave their consent, and the Board obtained the other two patients' records via administrative subpoena. Based on these records, MBC filed an accusation against Dr. Lewis based on the original complaint and the five additional patients, alleging unprofessional conduct, prescribing dangerous drugs without an appropriate examination, excessive prescribing, and failure to maintain adequate and accurate medical records.

Prior to the administrative hearing, Dr. Lewis moved to dismiss MBC's allegations related to the five additional patients; he argued that by obtaining the CURES reports without a warrant, subpoena, or good cause, MBC violated his patients' privacy rights. An ALJ denied Dr. Lewis's motion, stating that the Board's interest in obtaining the reports in a highly regulated area outweighed the invasion of privacy.

Following an evidentiary hearing, the ALJ concluded that Dr. Lewis engaged in unprofessional conduct and repeated negligent acts and failed to maintain adequate medical records. The ALJ recommended revoking Dr. Lewis's license but staying the revocation and placing Lewis on probation for three years; MBC adopted the ALJ's recommendation.

Dr. Lewis filed a writ of administrative mandamus in superior court seeking to set aside MBC's decision; the superior court denied his petition. Dr. Lewis next filed a petition for extraordinary writ in the court of appeal, again asserting his patients' right to informational privacy in their controlled substances prescription records. The court of appeal found that (1) Dr. Lewis did not satisfy the threshold elements required to establish that the Board's actions involved a significant intrusion on a privacy interest protected by the state Constitution; and (2) "even if Lewis had satisfied the threshold elements to establish a privacy right on behalf of his patients, the invasion of privacy was justified because it furthered two compelling government interests: 'controlling the diversion and abuse of controlled substances' and 'protect[ing] the public against incompetent, impaired, or negligent physicians.'"

The Supreme Court unanimously affirmed the appellate court's decision. Although the Court found that Dr. Lewis had standing to assert his patients' privacy rights in certain cases, it rejected his constitutional claim. In its decision in *Hill v. National Collegiate Athletic Association*, 7 Cal. 4th 1 (1994), the Court articulated a two-part inquiry for determining whether the right to privacy under article I, section 1 has been violated. First, the complaining party must meet three "threshold elements" utilized to screen out claims that do not involve a significant intrusion on a privacy right protected by the Constitution. The party must demonstrate (1) a legally protected privacy right; (2) a reasonable

expectation of privacy under the circumstances; and (3) conduct by defendant constituting a serious invasion of privacy. Second, if a claimant satisfies the threshold inquiry, the defendant may prevail by negating any of the three elements discussed above or by pleading and proving, as an affirmative defense, that the invasion of privacy is justified because it substantively furthers one or more countervailing interests.

Here, the Supreme Court—applying a general balancing test—rejected Dr. Lewis's argument that MBC violated his patients' privacy rights because it found that MBC's review of Dr. Lewis's CURES records "was justified by the state's dual interest in protecting the public from the unlawful use and diversion of a particularly dangerous class of prescription drugs and protecting patients from negligent or incompetent physicians." The Court held that MBC's actions in this matter did not implicate a "fundamental autonomy right" of Dr. Lewis's patients; as a result, MBC was not required to demonstrate a "compelling state interest," nor was it required to show that "it adopted the least intrusive means of achieving its legitimate objectives." The Court rejected Dr. Lewis's citation to several cases involving Board access to a patient's medical records, noting that "medical records" are privileged and contain far more sensitive information than do prescription records. "Moreover, a reasonable patient would know or should know that the government monitors the sale and distribution of controlled substances, and that prescription records are routinely reviewed by pharmacists and insurance companies. The same cannot be said of a patient's comprehensive medical record." The same distinction, the Court ruled, applies to Dr. Lewis's contention that MBC should have to show good cause before accessing CURES records:

We agree [with MBC] that a good cause requirement would compromise the Board's ability to identify and address potentially dangerous prescribing practices. ...Patients who objected to subpoenas to compel disclosure of their medical records on the ground that the Board lacked good cause have stalled investigations in the past. Such delay is tolerated in that context because of the heightened privacy interests implicated by government searches of medical records. For prescription records, however, delays of that magnitude would impede the Board's ability to swiftly identify and stop dangerous prescribing practices.

Lewis, 3 Cal. 5th at 575-76. The Court also found that several provisions in both the Medical Practice Act and in the Health and Safety Code governing CURES provide safeguards that limit the degree to which patients' privacy is invaded when the Board examines their prescription records.

Thus, applying a general balancing test, the Court found

that the balance tips in favor of the Board's interest in protecting the public from unlawful use and diversion of a particularly dangerous class of prescription drugs and protecting patients from negligent or incompetent physicians. Because any potential invasion of privacy caused by the Board's actions was justified by countervailing interests, we conclude that the Board did not violate article I, section 1 of the California Constitution when it obtained patient prescription records from CURES.

Lewis. 3 Cal. 5th at 575.

In *Cross v. Superior Court*, 11 Cal. App. 5th 305 (May 1, 2017), the Second District Court of Appeal held the psychotherapist-patient privilege in Evidence Code sections 1010 and 1014 does not protect patient records from disclosure when sought as part of a MBC disciplinary investigation into whether a psychiatrist improperly prescribed a controlled substances.

In May 2014, MBC received a complaint against psychiatrist Alisa Cross alleging overprescribing of psychotropic medication. MBC staff in the Consumer Complaint Unit obtained a CURES report and referred the matter to HQIU for formal investigation. HQIU medical consultant Dr. Cheryl Gray, who is board-certified in internal medicine, reviewed

the CURES report in an effort to identify patients to whom Dr. Cross may have been overprescribing prescription drugs. Dr. Gray identified three individuals who may have been prescribed a controlled substance by Dr. Cross that was inconsistent with the standard of care. In each of the three cases, Dr. Cross had prescribed more than the daily maximum dosage of Schedule II controlled substances used to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy. HQIU mailed release forms to the three patients which, if signed, would authorize MBC to obtain their medical and psychiatric records from Dr. Cross for use in the Board's investigation; HQIU indicated that if the patients did not consent, it would subpoen the records. HQIU received no response from two of the three patients; the third patient, when reached by telephone, denied ever having been treated by Dr. Cross.

Thus, DCA issued subpoenas for the medical records of the three patients and served them on Dr. Cross. Through counsel, Dr. Cross declined to produce any of the subpoenaed records. She asserted that she had contacted two of the patients and they did not consent to their records being released to the Board; she was unable to reach the patient who told HQIU that she had never been treated by Dr. Cross. Thus, Dr. Cross took the position that she was unable to release the subpoenaed records in light of the physician-patient and psychotherapist-patient privileges.

DCA filed a motion to compel compliance with the subpoenas in superior court; accompanying the motion was a declaration from Dr. Gray in which she opined that Dr. Cross's prescription patterns for the three patients, "in the absence of any other information, appear to represent concerning departures from the standard of care" for prescribing the central nervous system stimulants at issue, which have "a high potential for

abuse." In Dr. Gray's opinion, any circumstances or conditions that would require dosages or quantities of the prescribed stimulants outside the customary range should be documented by the prescribing physician. Dr. Cross opposed DCA's motion for two reasons: first, Dr. Cross claimed the records were protected by psychotherapist-patient privilege; and second, Dr. Cross claimed even if the privilege did not apply, DCA had not shown good cause that would overcome the patients' constitutional right to privacy in their medical records. Dr. Cross supported her opposition with a declaration of her own, in which she attacked Dr. Gray's qualifications inasmuch as Dr. Gray is "a general practice physician" and not a psychiatrist. After reviewing the case, the superior court concluded the psychotherapist-patient privilege does not protect the subpoenaed records because Business and Professions Code section 2225 annuls the privilege for purposes of a MBC disciplinary investigation.

Dr. Cross then filed a petition for writ in with the Second District Court of Appeal seeking reversal of the superior court's decision. The appellate court affirmed the superior court's decision that the psychotherapist-patient privilege does not protect the subpoenaed records because Business and Professions Code section 2225 abrogates that privilege for purposes of a MBC disciplinary investigation, but additionally found that a psychiatric patient's constitutional right to privacy requires DCA to demonstrate that a subpoena for a patient's records is supported by a compelling interest and that the information demanded is relevant and material.

On the first issue presented, the Court analyzed the interaction of Business and Professions Code section 2225 and the privilege provision of Evidence Code section 1010, which defines the psychotherapist-client privilege. In this matter, the court found that there

is no dispute that the records subpoenaed by DCA fall within the psychotherapist-client privilege sections of the Evidence Code. The court also drew on legislative history in making a distinction between the physician-patient privilege and the psychotherapist-patient privilege, finding that the enactment of the Evidence Code in 1965 "establishes a new privilege that grants to patients of psychiatrists a privilege much broader in scope than the ordinary physician-patient privilege." However, section 2225(a)—a later-enacted statute—states that the provisions of "any other law making a communication between a physician...and his or her patients a privileged communication" do not apply in an investigation conducted pursuant to the provisions of the Medical Practice Act. The court reached this conclusion through the well-established principles of law that a statute enacted later in time controls over an earlier-enacted statute and that a specific statute prevails over a more general statute. Here, Business and Professions Code section 2225 is both later and more specific than the provision of the Evidence Code related to psychotherapist-client privilege.

The court then addressed the second issue presented whether patients have a state constitutional right to privacy that protects information contained in their medical records. Although the court found patients do have a right to privacy in their medical records, this right may be overcome by a showing of a compelling state interest. Here, MBC advanced the compelling state interest in the investigation into excessive or improper prescribing of controlled substances; in fact, the legislature itself in Business and Professions Code section 2220.05(a)(3) has emphasized the importance of such investigations by directing MBC to prioritize its resources to address the harm of controlled substances. While the court found that MBC had demonstrated a compelling state interest, it also found that

DCA's subpoenas must be narrowly tailored. In this regard, the court found that certain portions of the subpoenas were too broad and thus granted the petition to enforce the subpoenas only to the extent that DCA's document requests were "relevant and material" to the investigation being conducted.

On July 26, 2017, the California Supreme Court of California denied Dr. Cross's petition for review.

RECENT MEETINGS

At MBC's April 2017 meeting, Board President Dr. GnanaDev discussed how he and Board Vice-President Denise Pines had been working closely with Board staff to prepare for the Board's sunset review hearing. Dr. GnanaDev stated that after the hearing, he and Ms. Pines worked with Board staff to prepare <u>written responses</u> to the issues raised in the legislative background paper.

At its July 2017 meeting, MBC reelected Dr. Dev GnanaDev as Board President; public member Denise Pines as Vice-President; and Dr. Ronald Lewis as Board Secretary for another year.