BACKGROUND PAPER FOR The Medical Board of California

Joint Sunset Review Oversight Hearing, March 19, 2021 Senate Committee on Business, Professions, and Economic Development and Assembly Committee on Business and Professions

IDENTIFIED ISSUES, BACKGROUND AND RECOMMENDATIONS REGARDING THE MEDICAL BOARD OF CALIFORNIA

BRIEF OVERVIEW OF THE MEDICAL BOARD OF CALIFORNIA

History and Function of the Medical Board of California

The Medical Board of California (MBC)'s history dates back to 1876 with the passage of the first Medical Practice Act (Act). In 1901, the Act was completely rewritten and the former California Medical Society Board, the Eclectic Medical Society Board, and the Homeopathic Medical Society Board merged to become the Board of Examinations (Board) comprised of nine members. The membership was increased to 11 in 1907, and in 1913, a revolving fund was created to fund the Board's activities. From 1950 to 1976, the Board expanded its role beyond physician licensing and discipline to oversee various allied health professions. In 1976, significant changes were made to the Act to create MBC much as it exists today, as well as adjustments to MBC's composition. The prior Board's 11 members included only one non-physician member but MBC's membership increased to 19 members, including seven public members. MBC underwent a structural change in 2008 with the elimination of its Division of Licensing and Division of Medical Quality and the establishment of one unified board with membership set at 15.

The current MBC mission statement, as stated in its 2018 Strategic Plan, is as follows:

The mission of the Medical Board of California is to protect health care consumers through the proper licensing and regulation of physicians and surgeons and certain allied health care professions and through the vigorous, objective enforcement of the Medical Practice Act, and to promote access to quality medical care through the Board's licensing and regulatory functions.

Through the Act, MBC has jurisdiction over physicians and surgeons, as well as special program registrants/organizations and special faculty permits which allow those who are not MBC licensees but meet licensure exemption criteria outlined in the Act to perform duties in specified settings. MBC also has statutory and regulatory authority over licensed midwives, medical assistants, registered polysomnographic trainees, registered polysomnographic technicians, registered polysomnographic technologists, research psychoanalysts, and student research psychoanalysts. MBC also approves accreditation agencies that accredit outpatient surgery settings and issues Fictitious Name Permits to physicians practicing under a name other than their own.

MBC has a large organization with various units to allow MBC to carry out its mission. Through its licensing program, MBC ensures that only qualified applicants, pursuant to the requirements in the Act and related regulations, receive a license or registration to practice. The licensing program has a Consumer Information Unit (CIU) that serves as a call center for all incoming calls to MBC. Via its enforcement program, allegations of wrongdoing are investigated and disciplinary or administrative action is taken as appropriate. MBC's Central Complaint Unit (CCU) receives and triages all complaints. If it appears that a violation may have occurred, the complaint is either transferred to the Department of Consumer Affairs (DCA)'s Division of Investigation, Health Quality Investigation Unit (HQIU), which includes sworn peace officers, or to MBC's own Complaint Investigation Office (CIO), which is comprised of non-sworn special investigators. Investigators investigate the complaint and, if warranted, refer the case for disciplinary action. MBC's Discipline Coordination Unit processes all disciplinary documents and monitors cases that have been referred for formal discipline to the Office of the Attorney General (OAG), which serves as MBC's prosecuting attorney. If a licensee or registrant is placed on probation, MBC's probation unit monitors the individual while they are on probation to ensure they are complying with the terms and conditions of probation. The Probation Unit is comprised of inspectors who are located throughout the state, housed within various field offices. Having inspectors throughout the state helps eliminate excess travel and enables probationers to have face-to-face meetings with the inspectors for monitoring purposes. MBC has its own Information Systems Branch (ISB) that performs information technology functions and assists in finding technological improvements to streamline MBC's enforcement and licensing processes. As MBC engages in a number of activities to educate physicians, applicants, and the public, the Office of Legislative and Public Affairs provides information to physicians, as well as applicants, regarding MBC functions, laws, and regulations.

MBC is comprised of 15 members: eight physicians and seven public members. All eight professional members and five of the public members are appointed by the Governor. One public member of the Board is appointed by the Senate Committee on Rules and one public member is appointed by the Speaker of the Assembly. Current law requires that four of the physician members hold faculty appointments in a clinical department of an approved medical school in the state, but no more than four members may hold full-time appointments to the faculties of such medical schools. The Board meets about four times per year. MBC members receive a \$100-a-day per diem. All meetings are subject to the Bagley-Keene Open Meetings Act. MBC's composition is further discussed in Issue #1.

The following is a listing of the current MBC members:

Board Member	Appointment Date	Term Expiration Date	Appointing Authority	Professional or Public
Kristina D. Lawson, J.D., President	October 28, 2015	June 1, 2022	Governor	Public
Kristina Daniel Lawson, of Walnut Creek,	0010001 20, 2013	1, 2022	Go (Cilio)	1 45110
has served as a public member of the Medical				
Board of California since 2015. Lawson is a				
partner at Hanson Bridgett LLP in Walnut				
Creek and San Francisco, where she practices				
land use and environmental law. Lawson was				
a member of the Walnut Creek City Council				
from 2010 to 2014, and served as Walnut				
Creek's Mayor in 2014.				
Howard Krauss, M.D., Vice President	August 20, 2013	June 1, 2021	Governor	Professional
Dr. Howard R. Krauss was appointed to the				
Medical Board in 2013 by Governor Edmund				

G. Brown Jr. He has been in the private practice of neurosurgical ophthalmology in Santa Monica since 1984. He is also Clinical Professor of Ophthalmology and Neurosurgery at the David Geffen School of Medicine at UCLA and Director of Ophthalmology for the Pacific Neuroscience Institute in Santa Monica. He is a Mentor Examiner, training Examiners for the American Board of Ophthalmology. He is a founding member and past member of the board of the North American Skull Base Society and currently serves on the board of the Pacific Neuroscience Institute Foundation. Prior to entering medical school he was a Systems Engineer with the Hughes Aircraft Space & Communications Group in El Segundo. He holds degrees in Electrical Engineering from The Cooper Union and Aeronautics & Astronautics from MIT.				
Randy Hawkins, M.D., Secretary Dr. Randy W. Hawkins has been in private practice since 1985. His medical practice is composed of primary care, pulmonary and critical care medicine, and hospice care. He is board certified in internal medicine and pulmonary and critical care medicine. He is clinical assistant professor of medicine at the Charles Drew University of Medicine and Science. Dr. Hawkins represents the Medical Board on the Health Professions Education Foundation. He is a member of a Food and Drug Administration Advisory Committee.	March 4, 2015	June 1, 2024	Governor	Professional
Ryan Brooks Mr. Brooks is the Executive Vice President of Government Affairs for Outfront Media, responsible for creating and maintaining governmental and public affairs activities, compliance, community outreach, policy direction and fundraising activities for the United States. Mr. Brooks' many appointments include Industry Trade Advisory Committee on Services and Financial Industries under the Obama Administration and reappointed under the Trump Administration. In 2003, Mr. Brooks was appointed by San Francisco Mayor Willie Brown, Jr. to the San Francisco Public Utilities Commission and reappointed by Mayor Gavin Newsom in 2004, serving as the Vice President in 2006 and President in 2007. Mr. Brooks served as the Director of Administrative Services for the City and County of San Francisco under the appointment of Mayor Willie L. Brown, Jr. Mr. Brooks was appointed by Governor	February 2, 2021	June 1, 2024	Governor	Public

Schwarzenegger in 2008 to the California Board of Pharmacy, and reappointed in 2010 and 2016 by Governor Jerry Brown. Mr. Brooks is a former member of the New Motor Vehicle Board as well as the Little Hoover Commission. Since 2003, Mr. Brooks has been a member of the California International Relations Foundation. The Foundation provides assistance to the California State Senate in furthering the exchange of economic, educational and cultural information between government leaders and other citizens of foreign countries.				
Alejandra Campoverdi Ms. Campoverdi is a nationally-recognized women's health advocate and former Obama White House official. An influential patient advocate for breast cancer and BRCA awareness, Ms. Campoverdi produced and appeared in Inheritance - a PBS health documentary that intimately follows the surgical journeys of three women who are genetically predisposed to breast cancer and has been named one of the "Best Documentaries of 2020" by ELLE. She is the founder of the Well Woman Coalition, an initiative empowering women of color to have agency over their own health through awareness, education, and advocacy. She also founded LATINX & BRCA in partnership with Penn Medicine's Basser Center for BRCA, which is the first awareness campaign on the BRCA gene mutation that targets Latinos and offers Spanish-language educational materials. From 2009-2012, Ms. Campoverdi served in the Obama White House, initially as Special Assistant to the Deputy Chief of Staff for Policy and later as White House Deputy Director of Hispanic Media. She is a former Commissioner for the California Children and Families Commission, also known as First 5 California. Ms. Campoverdi currently serves on the Boards of Harvard's Shorenstein Center on Media, Politics and Public Policy, the California Community Foundation, and the Harvard Kennedy School's Journal of Hispanic Policy, and is a member of the	September 30, 2020	June 1, 2024	Governor	Public
Pacific Council on International Policy. Dev GnanaDev, M.D. Dev GnanaDev, M.D., serves as chair of the Department of Surgery at Arrowhead Regional Medical Center, a position he has held since 1989. He is a clinical professor of surgery at Western University for Health Sciences and an associate professor of	December 21, 2011	June 1, 2022	Governor	Professional

surgery at Loma Linda University. He served as president of the California Medical Association from 2008 to 2009. Dr. GnanaDev has received a multitude of honors and recognition for his outstanding work and commitment to those who utilize public health programs, including the Medical Board's Physician Recognition Award in February 2005.				
Ronald Lewis, M.D. Dr. Lewis has been a physician and surgeon with the California Department of Corrections at Ironwood State Prison since 2008. He also has been an assistant clinical professor at the University of California, San Diego Department of Medicine since 2000. Prior to that, Dr. Lewis was an urgent care physician at Eisenhower Immediate Care from 2003 to 2008, and Sharp Rees-Stealy Medical Group from 2001 to 2004. Lewis was the director of medical affairs at Agouron Pharmaceuticals, Inc. from 1997 to 2001 and at Sequus Pharmaceuticals, Inc. from 1995 to 1997. He was a clinical assistant professor at Stanford University School of Medicine from 1993 to 1999, and held multiple positions at Syntex Laboratories, Inc. from 1987 to 1995, including associate director of medical services, senior associate director of medical services, and senior associate director, clinical investigation. Dr. Lewis was an emergency department physician at St. Mary's Hospital and Medical Center in San Francisco from 1985 to 1995.	August 20, 2013	June 1, 2021	Governor	Professional
Laurie Rose Lubiano, J.D. Laurie Rose Lubiano is an attorney licensed to practice law in the State of California and before the U.S. Patent & Trademark Office. She has been IP & Product Counsel for the Climate Corporation since 2017, where she handles a variety of matters including intellectual property, commercial agreements, international expansion and privacy compliance. Ms. Lubiano is a board member for the Mission Hiring Hall in San Francisco and a member of the National Asian Pacific American Bar Association and Asian American Bar Association of the Greater Bay Area. She is also the current President of the Filipino Bar Association of Northern California (FBANC) and founding member of the National Filipino American Lawyers Association. Ms. Lubiano also served on the Planning Commission for the City of Daly City for over 4 years.	December 17, 2018	June 1, 2024	Governor	Public

Asif Mahmood, M.D. Dr. Asif Mahmood comes from humble beginnings, growing up in the remote Pakistani village called Kharian. He received his medical degree from Sind Medical College, did his Internal Medicine residency at the University of Kentucky Medical Center followed a Pulmonary fellowship at the University of Virginia and Harlem Hospital at Columbia University. Dr. Mahmood has been a practicing physician at Huntington Memorial Hospital in Pasadena since 2000 and has served in different capacities from medical executive committee member to chief of staff in different hospitals. He is also on the board of the East Los Angeles College Foundation and the United Nations International Children's Fund, Western Region.	June 3, 2019	June 1, 2023	Governor	Professional
Richard E. Thorp, M.D. Dr. Thorp has been president and chief executive officer at Paradise Medical Group since 2001. He was an internal medicine physician and medical director for Butte County for the California Medical Foundation from 1994 to 2000 and internal medicine physician at Richard E. Thorp MD Inc. from 1981 to 1994. Dr. Thorp is a member of the American Medical Association, American College of Physicians, California Medical Association and the Butte-Glenn County Medical Association.	July 26, 2019	June 1, 2023	Governor	Professional
Cinthia Tirado, M.D. Dr. Cinthia Tirado has been an associate clinical professor in the Department of Anesthesiology at the University of California, Davis Medical Center since 2011. She is a member of the American Society of Anesthesiologists, California Medical Association, American Society of Regional Anesthesia and Pain Medicine, American Medical Association, and the California Society of Anesthesiologists.	June 15, 2020	June 1, 2021	Governor	Professional
Eserick "TJ" Watkins Eserick "TJ" Watkins previously served as a Board member on the Physical Therapy Board of California and held the vice president position. Mr. Watkins is the owner of The Next Level Coaching, a hybrid strength training and life coaching company. He also serves on the board of South Coast Foundation, a US-based private foundation that funds children infected and affected by HIV/AIDS in South Africa. Mr. Watkins is a published author, speaker and coach.	June 1, 2019	June 1, 2023	Senate Rules Committee	Public
Felix C. Yip, M.D. Dr. Felix C. Yip is a board certified urologist in private practice and is currently the Chief	January 30, 2013	June 1, 2022	Governor	Professional

of Staff at Garfield Medical Center.			
Presently he is serving as clinical professor of urology at the Keck School of Medicine - University of Southern California and has served as clinical assistant professor of surgery at UCLA School of Medicine and Western University of Health Sciences in prior years. Dr. Yip is a member of the Board of Counselors at UCLA School of Dentistry and a member of USC Keck Medicine Leadership Board.			
Vacant		Speaker of the Assembly	Public
vacant		Governor	Public
Vacant			
		Governor	Public
Vacant			

MBC has six standing committees, seven two-member task forces or issue specific committees, two panels and one council that assist with MBC's work. MBC committees may meet on an as-needed basis and may meet outside of the cycle of when quarterly MBC meetings are held, offering an easier pathway for interested parties to weigh in on a particular issue. The committee structure also allows committee members to have an expanded discussion on a noteworthy topic and potentially make a decision that moves forward as a formal recommendation to MBC for consideration at a MBC meeting. Pursuant to MBC's strategic plan, MBC must convene every other year to discuss the purpose of each committee and reevaluate the need for the committees/subcommittees/task forces created by MBC. The following is a list of MBC entities:

- Application Review and Special Programs Committee. Statutorily mandated, the committee evaluates the credentials of certain licensure applicants (such as those claiming postgraduate training hardship or those requesting a waiver from the written licensing exam waiver to determine their eligibility for licensure). The committee also provides guidance, recommendations and expertise regarding special program laws and regulations, specific applications, medical school site visits, and other issues of concern to the chief of licensing.
- Special Faculty Permit Review Committee. The purpose of this statutorily mandated committee is to evaluate the credentials of internationally trained physicians sponsored by a California medical school to determine if he or she is academically eminent in his or her field of specialty and should be issued a Special Faculty Permit under Section 2168 of the Business and Professions Code (BPC), which authorizes the physician to practice with all the rights and privileges of a California medical license in the sponsoring medical school and its formally affiliated hospitals. The committee submits a recommendation to MBC for each proposed candidate for final approval or denial.
- Midwifery Advisory Council. The Council is statutorily defined in BPC Section 2509 and serves as a formal, permanent body to provide MBC with input from those in the midwifery profession as well as to develop solutions to various regulatory, policy and procedure issues regarding the licensure and regulation of midwives by MBC.

- Panels A and B. Panels created under MBC's statutory authority in BPC 2008 to appoint panels from its members to evaluate appropriate disciplinary actions. Panel A considers actions related to physicians with a last name starting with A-L and Panel B considers actions related to physicians with a last name starting with M-Z.
- Executive Committee. The Executive Committee's purpose is to oversee various administrative functions of the MBC such as budgets and personnel, strategic planning and reviewing legislation.
- Licensing Committee. The Licensing Committee serves as an expert resource and advisory body to MBC members and the MBC licensing program by educating MBC members and the public on the licensing process. The Executive Committee provides recommendations to the full Board, annually evaluates the performance of the executive director, and acts for the Board in emergency circumstances (as determined by the chair, and as allowed by law) when the full Board cannot be convened.
- Enforcement Committee. The Enforcement Committee is an expert resource and advisory body to MBC members and the MBC enforcement program, educating MBC members and the public on enforcement processes. It also serves to identify program improvements in order to enhance protection of healthcare consumers and review enforcement regulations, policies, and procedures.
- Public Outreach, Education and Wellness Committee. The Public Outreach, Education and Wellness Committee develops informational materials on important issues that MBC, develops and monitors MBC's outreach plan, monitors MBC's strategic communications plan and develops physician wellness information by identifying available activities and resources that renew and balance a physician's personal and professional life.
- *Editorial Committee*. The Editorial Committee reviews MBC's Newsletter articles to ensure they are appropriate for publication and provides any necessary edits to the articles.
- *Midwifery Task Force*. The Midwifery Task Force reviews current laws and regulations for licensed midwives and acts as a liaison with the Midwifery Advisory Council on issues that may come before MBC.
- *Prescribing Task Force*. The Prescribing Task Force's aim is to identify ways to proactively approach and find solutions to the epidemic of prescription drug misuse, abuse and overdoses, as well as inappropriate prescribing of prescription drugs, through education, prevention, best practices, communication and outreach.
- Sunset Review Task Force. The Sunset Review Task Force meets with MBC's executive director and deputy director to review sunset review questions and responses.
- Disciplinary Demographic Task Force. The goal of this task force is to evaluate claims of discrimination and the findings of the California Research Bureau's demographic study in order to proactively prevent bias in any and all Board processes and any actions of anyone who may be involved in the investigative or disciplinary process.

- Stem Cell and Regenerative Medicine Task Force. This task force receives information and input from interested parties on options pertaining to stem cell treatments, to promote consumer protection within the Board's authority.
- Compounding Task Force. This task force receives information and input form interested parties pertaining to physician compounding activities, to promote consumer protection within the Board's authority.

In order to remain current with national trends in medicine, MBC is involved in various national associations and organizations. Several MBC members and the executive director sit on committees for national associations and organizations in order to provide input and perspective from California, given that the state has the largest number of licensed physicians in the nation and the activities and functions of MBC have an impact nationally. MBC is a voting member of the Federation of State Medical Boards, a national nonprofit organization representing the 70 medical and osteopathic boards in the United States and its territories. MBC is also a member of the Administrators in Medicine, a national not-for-profit organization for state medical and osteopathic board executives. MBC is additionally a member of the Educational Commission for Foreign Medical Graduates (ECFMG), a private, nonprofit organization whose mission is to promote quality health care for the public by certifying international medical graduates for entry into U.S. graduate medical education, and by participating in the evaluation and certification of other physicians and health care professionals nationally and internationally. MBC is also a member of the International Association of Medical Regulatory Authorities, an organization that encourages best practices among medical regulatory authorities worldwide in the achievement of their mandate to protect, promote and maintain the health and safety of the public by ensuring proper standards for the profession of medicine. Additionally, MBC is a member of the Citizen Advocacy Center whose mission is to increase the accountability and effectiveness of health care regulatory, credentialing, oversight and governing boards by advocating for a significant number of public members, improving the training and effectiveness of public and other board members, developing and advancing positions on relevant administrative and policy issues, providing training and discussion forums, and performing needed clearinghouse functions for public members and other interested parties.

MBC reports that it engages in a number of activities to educate physicians, applicants for licensure, and the public and notes that its website and the information it provides to consumers has been ranked top in the nation by *Consumer Reports*. MBC states that it uses the internet in innovative ways to provide information to the public and licensees regarding meetings, initiatives, and laws and regulations regarding the practice of medicine in California. MBC's website is its main information hub, and the Board advises that the website is consistently updated with fresh content. MBC uses its website, subscription list, licensee/applicant email service, podcast, iOS phone app, quarterly newsletter, and Twitter, Facebook and YouTube accounts to deliver timely, accurate and relevant information to stakeholders.

MBC posts agendas for all Board and committee meetings, including related agenda materials, on its website; meeting agendas are posted at least 10 days prior to the meeting, and meeting materials are added as they become available. By visiting MBC's website, stakeholders can sign up to receive alerts to their email inboxes pertaining to various informational topics including Board meeting information, Newsletters and news releases, proposed regulations, and Board enforcement actions. MBC uses social media to further provide information about meetings, make press releases available, provide law and regulation updates, notify licensees about continuing medical education (CME) opportunities,

make important public health updates accessible, and significantly, ensure that disciplinary actions taken against violating physicians and surgeons are made public.

In May 2018, MBC launched its podcast, "Medical Board Chat," making MBC the first licensing board within DCA to use this form of outreach. In summer 2018, MBC launched its License Alert Mobile App for Apple iOS devices, creating a new method to inform licensees and consumers about Board activities. Developed entirely by MBC staff, the free mobile app allows consumers to follow the licensees of up to 16 physicians and receive notifications when there has been an update to any of their profiles. The app sends an alert directly to the smartphones of consumers, alerting them to any change to the licensee's status, including when accusations or disciplinary orders are published. The app is the first of its kind among the medical boards in the nation and is another tool MBC uses to interact with the public. MBC advises that it will continue to find innovative ways of communicating with stakeholders, while leveraging existing technology to inform the public.

Fiscal, Fund and Fee Analysis

MBC is a special fund agency whose activities are funded through regulatory fees and license fees. MBC will not comply with a statutory mandate to maintain two to four months' reserve in its fund by the end of FY 20/21. At the end of FY 19/20, MBC had a fund reserve of \$18,919,000 which equates to a 3.1 months' reserve, just keeping the Board within its statutory mandate. However, it is projected that by the end of FY 20/21, MBC will have a fund reserve of \$9,253,000 equating to 1.4 months' reserve, and by the end of FY 21/22 the Board will have a fund reserve of \$4,672,000 equating to a 0.7 months' reserve. The fund includes a Control Section 14.00 loan (a loan between Department special funds) of \$12 million to the Medical Board Contingent Fund in FY 21/22 to ensure the Board has enough cash flow to continue operations until a fee increase can be secured.

The following is the past, current and projected fund condition for MBC, as indicated in the MBC sunset report:

Fund Condition						
(Dollars in Thousands)	FY	FY	FY	FY	FY	FY
(Dollars III Thousands)	16/17	17/18	18/19	19/20	20/21	21/22
Beginning Balance ¹	\$27,242	\$28,728	\$33,739	\$26,297	\$18,919	\$7,388
Revenues and Transfers	\$64,863	\$65,928	\$59,892	\$59,761	\$66,036	\$58,002
Inter-departmental Loan	\$0	\$0	\$0	\$0	\$0	\$12,000
Total Revenue	\$92,105	\$94,656	\$93,631	\$86,058	\$84,955	\$65,390
1111 Expenditures ²	\$60,307	\$62,689	\$62,072	\$62,755	\$73,554	\$75,761
Direct to Fund Pro Rata	\$3,070	\$3,802	\$4,404	\$4,384	\$4,013	\$4,013
Loans to General Fund	\$0	\$0	\$0	\$0	\$0	\$0
Accrued Interest, Loans to General Fund	\$0	\$0	\$0	\$0	\$0	\$0
Loans Repaid From General Fund	\$0	\$0	\$0	\$0	\$0	\$0
Fund Balance	\$28,728	\$28,165	\$27,155	\$18,919	\$7,388	-\$14,384
Months in Reserve	5.2	5.1	4.7	3.1	1.1	-2.2

- 1 Beginning balance is the Adjusted Beginning Balance of the Fund Condition Statement which includes the prior year adjustment and fund assessment adjustments.
- 2 Expenditures are net of the state operations, scheduled and unscheduled reimbursements, and statewide assessments. FYs 2020/2021 and 2021/22 expenditures (and revenues) are projections.

Total Revenue, Expenditure and Fund Balance/Reserve update: (FM7-January)*

	FY	FY	FY
	19/20	20/21	21/22
Total Revenue	\$86,058	\$81,399	\$83,493
Total Expenditure	\$67,139	\$72,146	\$78,821
Fund Balance	\$18,919	\$9,253	\$4,672
Months in Reserve projection	3.1	1.4	0.7

Note:

- 1. Projected fund balance at the end of current fiscal year 20/21 is \$9.253 million, a net increase from previous estimates in the amount of 1.865 million dollars and months in reserve estimate increases to 1.4 months as compared to 1.1 previously reported still below statutory mandate of 2 to 4 months reserve.
- 2. FY 21/22 estimates includes Inter-department loan of \$12 million. However, updated estimates show a near insolvency conditions in the fund balance and months in reserve.

MBC's primary source of revenue, accounting for over 80 percent of the money MBC brings in, is physician license renewal fees. Both the fees for the allied health programs regulated by MBC and physician license renewal fee have remained the same since MBC's last review. MBC raised the initial physician and surgeon licensure fees, as well as those renewal fees, in 2006, the first increase since 1994, in order to support MBC's Vertical Enforcement/Prosecution model. Fees were decreased in 2008 when MBC eliminated its Diversion Program. Renewal fees were increased by \$12 in 2014, pursuant to SB 809 (DeSaulnier, Chapter 400, Statutes of 2013) which provided ongoing funding for California's Controlled Substances Utilization Review and Evaluation System (CURES) Prescription Drug Monitoring Program (PDMP) through health professional licensing fees. Pursuant to AB 3330 (Calderon, Chapter 359, Statutes of 2020) the CURES fee is scheduled to increase to \$22 per renewal cycle beginning April 1, 2021, and will decrease to \$18 beginning April 1, 2023. MBC collects the CURES fee and transfers the fee amount per renewed licensee to the Department of Justice (DOJ) which maintains the CURES system.

Effective January 1, 2007, the physician's initial licensure and renewal fees were increased by \$15 to \$805, based upon the average amount of cost recovery that MBC had received in the prior three fiscal years that would no longer be received by MBC due to its statutory inability to recover enforcement costs from licensees facing disciplinary action. Cost recovery is further discussed in Issue # 8 below.

At the time of initial licensure and renewal of a physician license, MBC collects \$25, which is transferred to the Health Professions Education Foundation (HPEF) to help fund the Steven M. Thompson California Physician Corps Loan Repayment Program that is administrated by HPEF. The loan repayment program encourages recently licensed physicians to practice in underserved locations in California by authorizing a plan for repayment of their student loans in exchange for their service in a designated medically underserved area for a minimum of three years. There is a requirement that most participants be selected from the specialty areas of family practice, internal medicine, pediatrics, and obstetrics/gynecology. However, up to 20 percent of the participants may be selected from other specialty areas. In addition, physicians and surgeons, at the time of initial licensure or renewal may contribute money to provide training for family physicians and other primary-care providers who will serve in medically underserved areas. The funds MBC collects for this family physician training program is transferred to the Office of Statewide Health Planning and Development (OSHPD)

Fee Schedule and Revenue (revenue					ars in thousa	ands)		
Fee	Current Fee Amount	Statutory Limit	FY 2016/2017 Revenue	FY 2017/2018 Revenue	FY 2018/2019 Revenue	FY 2019/2020 Revenue	% of Total Revenue	
(CONTINGENT FUND OF THE MEDICAL BOARD OF CALIFORNIA PHYSICIANS AND SURGEONS ONLY							
Application Fee (BPC 2435)	442.00	442.00	3,514	3,543	3,342	2,481	5.66%	
Initial License Fee (BPC 2435) (16 CCR 1351.5)	783.00	790.00	2,046	1,956	2,000	2,159	3.59%	
Initial License Fee (Reduced) (BPC 2435)	391.50	395.00	1,672	1,716	1,680	1,255	2.78%	
Biennial Renewal Fee (BPC 2435) (16 CCR 1352)	783.00	790.00	48,537	50,278	50,602	50,612	87.97%	

Revenues and Reimbursements		
Physician & Surgeon Renewals	\$50,612,0	00 81%
Application & Initial License Fees	5,901,00	00 9%
Reimbursements	3,096,0	00 5%
Other Regulatory Fees, Delinquency/Penalty/ Reinstatement Fees, Interest on Fund, Miscellaneous	3,247,00	5%
Total ¹	\$ 62,856,0	00 100%

1 Includes revenues and reimbursements. In Table 2, reimbursements are reflected as a reduction in Expenditures.

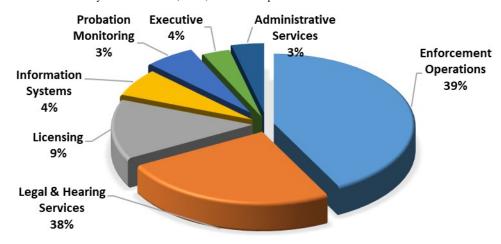
The Enforcement Program (including OAG costs, the Office of Administrative Hearings (OAH), the HQIU, and Probation Monitoring) makes up approximately 80 percent of the MBC's overall expenditures. Although MBC cannot order cost recovery for investigation and prosecution of a case, MBC is still authorized to order that probation monitoring costs be reimbursed. The Licensing Program accounts for approximately nine percent of the Board's expenditures, while the ISB accounts for approximately four percent. The Executive and Administrative Programs make up the remaining seven percent of the Board's overall expenditures.

Expenditures by Program Component			onent (dollars in thousands)					
	FY 2010	6/2017	FY 201	7/2018	18 FY 2018/2019		FY 2019/2020	
	Personnel Services	OE&E	Personnel Services	OE&E	Personnel Services	OE&E	Personnel Services	OE&E
Enforcement	\$6,651	\$37,846	\$6,914	\$40,275	\$6,869	\$40,339	\$7,504	\$38,547
Examination	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Licensing	\$4,564	\$2,043	\$4,269	\$2,034	\$4,402	\$1,853	\$4,510	\$2,188
Administration *	\$2,532	\$616	\$2,690	\$666	\$3,009	\$709	\$2,692	\$2,749
Information Systems	\$1,826	\$662	\$2,221	\$352	\$2,242	\$509	\$2,052	\$614
DCA Pro Rata	\$0	\$6,278	\$0	\$4,906	\$0	\$5,140	\$0	\$5,512
Diversion (N/A)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
TOTALS	\$15,573	\$47,445	\$16,094	\$48,233	\$16,522	\$48,550	\$16,758	\$49,610
*Administration inc	ludes costs fo	r executive s	staff, board, a	dministrative	support, and	fiscal service	es.	

Budget Distribution (budgeted, not actual)							
Enforcement Operations*	\$30,114,000	39%					
Legal & Hearing Services**	29,764,000	38%					
Licensing*	6,747,000	9%					
Information Systems	3,330,000	4%					
Probation Monitoring*	2,634,000	3%					
Administrative Services	2,190,000	3%					
Executive	3,077,000	4%					
Total	\$77,856,000	100%					

^{*} Budget amounts were adjusted for Attorney General Services, OAH, and Court Reporter Services.

^{**} Includes Attorney General Services, OAH, and Court Reporter Services.



MBC's budget, fees, and fund condition are further discussed in Issue #9 below.

Staffing Levels

MBC is currently authorized in the Governor's 2021/2022 budget for a total of 178.2 permanent positions and 10.1 temporary positions.

MBC notes that it is continuing its efforts to recruit and retain employees in each of its programs. In FY 2016/2017 and FY 2017/2018, MBC had an eight percent vacancy rate which increased to ten percent in FY 2018/2019. This past year, in FY 2019/2020 the Board had a slight increase to 12 percent. MBC's vacancy rate is currently at 10.6 percent, which equates to 20 vacant positions, and MBC advises that it continues to advertise its vacant positions, schedule interviews and process hiring packages as quickly as possible. MBC notes that as the duties for particular positions evolve due to operational need, MBC works with the DCA Office of Human Resources to reclassify its positions to ensure the efficient utilization of resources to enhance operations. MBC regularly conducts a review of its staff and reclassifies positions as needed in order to address the increased complexity of assignments, levels of responsibility and consequences involved, and the need for staff oversight and professional development. MBC uses policy and procedure manuals to ensure succession planning and, when available, has the individuals leaving a position provide training to new staff in order to ensure the transfer of a particular knowledge base. MBC states it does everything it can with its existing resources to ensure that new staff receive the training needed to be successful.

Licensing

MBC's licensing program ensures licenses or registrations are only issued to applicants who meet legal and regulatory requirements and who are not precluded from licensure based on past incidents or activities. As of June 30, 2020, MBC 152,402 physician and surgeon licensees, an approximate 7 percent increase since the last sunset review. Over the past four years, MBC received over 29,000 new physician and surgeon applications, issued over 26,000 physician and surgeon licenses, and renewed over 281,338 physician and surgeon licenses.

In addition to physicians, MBC licenses and/or issues registrations or permits for special faculty at medical schools, special programs, licensed midwives, research psychoanalysts and student research psychoanalysts, and polysomnographic trainees, technicians and technologists. (MBC's regulation of other allied health professionals is discussed below.) MBC also has responsibility for other approvals and permits. MBC approves outpatient setting accreditation agencies that accredit specific types of outpatient surgery centers that many licensed physicians use when performing surgical procedures. MBC also issues Fictitious Name Permits that allow physicians to practice medicine under a name other than their own.

MBC identifies applicants who indicate they are military service veterans or spouses through submission of documentation proving military status. Between FY 16/19 and 19/20, MBC received 45 physician applications for waivers from professional license renewal fees and continuing education requirements for physicians requesting Military status, pursuant to BPC Section 2440. MBC also received 45 physician applications that qualified for the expedited license available to military spouses and domestic partners of a military member who is on active duty in California pursuant to BPC Section 115.5.

MBC notes that it does not have a mechanism to quantify the number of applicants who offered military education, training, and experience toward meeting licensing requirements, since the Board accepts all medical schools approved by the LCME and all postgraduate training approved by the

ACGME, and does not differentiate between military and non-military education, training, and experience, as there are overlapping requirements.

Medical schools accredited by a national accrediting agency approved by MBC and recognized by the United States Department of Education are deemed approved by MBC. The Liaison Committee on Medical Education (LCME) is the nationally-recognized accrediting authority for allopathic medical education programs leading to the issuance of Medical Doctor (M.D.) degrees in the U.S. and Canada. MBC previously also approved international medical schools but pursuant to SB 798 (Hill, Chapter 775, Statutes of 2017), MBC does not conduct an independent review of these programs and instead recognizes applicants from a school outside of the U.S. or Canada if the school has been evaluated by the ECFMG (or one of the ECFMG-authorized international medical school accreditation agencies) and meets minimum requirements of medical schools accredited by either the LCME, the Committee on Accreditation of Canadian Medical Schools, or the Commission on Osteopathic College Accreditation. International graduates are also eligible for licensure if the foreign medical school they attended is listed on the World Federation for Medical Education (WFME) and the Foundation for Advancement of International Medical Education and Research (FAIMER) World Directory of Medical Schools joint directory or the World Directory of Medical Schools or if the school had been previously approved by MBC (this provision expires in 2027).

Physician applicants for licensure by MBC must pass nationally recognized examinations, the United States Medical Licensing Examination (USMLE) Step 1, Step 2 Clinical Knowledge (CK) and Step 3. Effective February 4, 2021, the Federation of State Medical Boards (FSMB) discontinued the USMLE Step 2 Clinical Skills (CS) examination that was suspended May 2020, due to COVID-19. The examination encompasses basic sciences, medical knowledge, patient diagnosis and treatment as well as practical knowledge by testing core areas of medicine, surgery, psychiatry, obstetrics/gynecology, pediatrics and family medicine. Examinations are offered throughout the world on an ongoing basis, although USMLE Step 3 is offered only in the US as a computer-based and mock patient-based. Applicants are eligible for USMLE Steps 1 and 2 CK upon satisfactory completion of specific basic science curriculum coursework. At the time of eligibility, the applicant participates in and completes the application process, ultimately gaining admittance to the examinations. Once the scores are released and the applicant has passed Step 1 and Steps 2 CK, the applicant continues with their medical education. The applicant is eligible for Step 3 immediately upon graduation from medical school. However, as this examination is practical and clinical based, many graduates prefer to complete at least one year of postgraduate training prior to attempting the Step 3 examination. Per USMLE requirements, applicants must complete the entire examination series, Steps 1 through 3, within seven years from the date of the first passing examination.

MBC requires documents to be sent directly from medical schools, postgraduate training programs, other state medical boards and other sources to MBC as means of verifying proof of attendance, completion, licensure in another state and other evidence that is necessary to consider for licensure. MBC notes that approximately 88 percent of the applications it receives and reviews are deficient at the time of review.

Until December 31, 2019, applicants for licensure from approved U.S./Canadian medical schools were required to have completed at least one year of approved postgraduate training to qualify for a physician license, while international graduates were required to have completed at least two years of postgraduate training. Effective January 1, 2020, all graduates of approved U.S./Canadian, or international medical schools are required to obtain 36 months of postgraduate training, which includes

24 months successfully completed in the same program, and submit documentation codified in statute and regulation to obtain a physician license.

All applicants must obtain fingerprint criminal record checks from both the Department of Justice (DOJ) and the Federal Bureau of Investigation prior to the issuance of a postgradutate training license and physician's medical license in California. If applicants respond affirmatively to a series of questions on the application related to issues during postgraduate training, unusual circumstances during medical school, or discipline, the applicant is able to provide narrative information to MBC and MBC requires that documentation supporting the applicant's assertion be provided directly to MBC. MBC also requires documentation to be provided directly to the board for proof of residency from medical education providers and previous medical licensure from the licensing agency. MBC queries the National Practitioner Databank, a confidential information clearinghouse created by Congress to improve health care quality, protect the public, and reduce health care fraud and abuse in the U.S., for certain applicants with issues of concern disclosed on the application or during the application process as well as applicants who disclose that he or she holds a license in another state, territory or province. MBC also queries all applicants in the FSMB database, which contains a record of disciplinary actions taken by other states and jurisdictions, as well as any inappropriate behavior in another state or jurisdiction during an examination. MBC does not recognize true reciprocity in that applicants for licensure in California must still adhere to certain medical school education requirements not present in all other states or jurisdictions.

Continuing Medical Education (CME)

Physicians are required to complete no less than 50 hours of approved CME during each two-year period immediately preceding the expiration date of his or her license. The only exception to this requirement is for a physician who takes and passes a certifying or recertifying examination administered by a recognized specialty board, the individual can be granted credit for four consecutive years of CME credit for purposes of licensure renewal. Upon renewal, physicians are required to self-certify under penalty of perjury that they have met each of the CME requirements, that they have met the conditions exempting them from all or part of the requirements, or that they hold a permanent CME waiver.

MBC CME requirements and considerations for courses have been updated since the prior review. Effective January 1, 2019, pursuant to AB 2487 (McCarty, Chapter 301, Statutes of 2018), all physicians licensed after January 1, 2019, may opt to complete a one-time mandatory 12-hour CME course on the treatment and management of opiate-dependent patients, which must include eight hours of training in buprenorphine treatment, or other similar medicinal treatment, for opioid use disorders, in lieu of the existing required CME on pain management under BPC section 2190.5. Physicians are required to take one of these CME courses. AB 1340 (Maienschein, Chapter 759, Statutes of 2017) allows for an optional CME 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; AB 1791 (Waldron and Gipson, Chapter 122, Statutes of 2018) allows for an optional CME course in integrating HIV/AIDS pre-exposure prophylaxis and post-exposure prophylaxis medication maintenance and counseling in primary care settings and; AB 845 (Maienschein, Chapter 220, Statutes of 2019) allows for an optional CME course in maternal mental health.

Pursuant to AB 241 (Kamlager-Dove, Chapter 417, Statutes of 2019), beginning January 1, 2022, all CME courses for physicians must contain curriculum that includes the understanding of implicit bias.

A CME course dedicated solely to research or other issues that does not have a direct patient care component or a course offered by a CME provider that is not located in California is not required to contain curriculum that includes implicit bias in the practice of medicine. Associations that accredit CME courses must ensure compliance with this requirement starting January 1, 2023.

At the time of the last sunset review, the Board was auditing one percent of the licensee population annually to confirm compliance with CME requirements. MBC requires that each physician retain records of all CME programs they completed for a minimum of four years in the event of a CME audit. In response to questions from the Committees about whether MBC has worked with DCA to receive primary source verification of CE completion through the Department's cloud, MBC advised that it has been in contact with the Accreditation Council for Continuing Medical Education (ACCME) on their data reporting system that would allow medical licensing regulatory agencies to access CME documents electronically.

In October 2018, MBC increased CME audits to ten percent of the licensee population annually. However, MBC was not able to maintain this high volume of audits on a monthly basis and notes it will be reducing the audit percentage to five percent. Currently, due to impacts from the COVID-19 pandemic on MBC operations, the CME audit program is entirely on hold while MBC resources are directed to essential services, particularly in light of a waiver issued (DCA Waiver DCA-20-53) that defers CE requirements for specified licensees.

MBC may also audit the actual CME courses or programs that licensees submit for credit, as well as any course or program about which MBC receives a complaint. In the event of an audit, course providers need to submit faculty curriculum vitae, the rationale for a course, the course content, course educational objectives, course teaching methods, evidence of evaluation, and records of attendance attendance records. Physicians will not receive CME credit for courses MBC determines are unacceptable following an audit.

Enforcement

MBC's enforcement activities are the core of its program, with the majority of its staff and resources dedicated to enforcement functions. Over the last three years, for all regulated license types, MBC has accomplished the following:

- Investigated and closed 32,793 and investigations
- Referred 1,887 cases to OAG for action
- Filed 1,192 accusations and/or petitions to revoke probation
- Obtained 232 suspension/restriction orders
- Revoked or accepted the surrender of 446 licenses
- Placed 513 licensees on probation
- Issued 248 public reprimands/public letters of reprimand.

The enforcement process begins with a complaint. Complaints are received from various sources, including the public, generated internally by MBC or based on information MBC receives from various entities through mandatory reports to MBC (mandatory reporting to MBC is discussed further in Issue #15 below). Over the prior four fiscal years, MBC received an average of 10,695 complaints against physicians and surgeons per fiscal year and reports that it has witnessed an increase in the number of complaints every year since the prior sunset review of MBC. Complaints are received by CCU which starts the process of determining next steps for a complaint. Complaints that pertain to treatment provided by a physician require medical records to be obtained. Pursuant to BPC Section 2220.08, before a quality of care complaint is referred for further investigation, it must be reviewed by one or more medical experts with the pertinent education, training, and expertise to evaluate the specific standards of care issues raised by the complaint to determine if further field investigation is required. When a medical reviewer determines a complaint warrants referral for further investigation, CCU transfers the complaint to the HQIU to be investigated by a sworn investigator, a peace officer. MBC notes there are 12 HQIU field offices located throughout California that handle these investigations. Complaints may also be forwarded to the Complaint Investigation Office (CIO) an internal unit at MBC comprised of non-sworn investigators. The CIO investigators handle complaints throughout the state from the Sacramento office.

MBC is required by law, BPC Section 129, to open a complaint within ten days of receipt and further required by law, BPC Section 2319, to set a goal of no more than 180 days between the time a complaint is received and the time a complaint is investigated. MBC is meeting the timeframe for opening complaints. In FY 2019/20, the overall average time MBC took to investigate a complaint was 202 days.

MBC's complaint priorities are outlined in BPC section 2220.05 in order to ensure that physicians representing the greatest threat of harm are identified and disciplined expeditiously. MBC must ensure that it is following this section of law when investigating complaints, including complaints alleging the following as being the highest priority:

- Gross negligence, incompetence, or repeated negligent acts that involve death or serious bodily injury to one or more patients, such that the physician and surgeon represents a danger to the public
- Drug or alcohol abuse by a physician and surgeon involving death or serious bodily injury to a patient
- Repeated acts of clearly excessive prescribing, furnishing, or administering of controlled substances, or repeated acts of prescribing, dispensing, or furnishing of controlled substances without a good faith prior examination of the patient and medical reason therefor
- Repeated acts of clearly excessive recommending of cannabis to patients for medical purposes, or repeated acts of recommending cannabis to patients for medical purposes without a good faith prior examination of the patient and a medical reason for the recommendation
- Sexual misconduct with one or more patients during a course of treatment or an examination,

- Practicing medicine while under the influence of drugs or alcohol; and
- Repeated acts of clearly excessive prescribing, furnishing, or administering psychotropic medications to a minor without a good faith prior examination of the patient and medical reason therefor.

The number of incoming complaints has continued to rise. In FY 2015/16, MBC received 8,679 complaints compared to 11,407 in FY 2018/19 and 10,868 in FY 2019/20. In FY 2019/20 the number of incoming complaints were on track to hit a new high until the start of the COVID- 19 pandemic statewide shutdown in mid-March 2020. The number of complaints dropped off significantly during the 4th quarter of FY 2019/20 and the year-end number for new complaints was down approximately 500 from the previous year. As the state reopens, MBC reports that it is seeing a return to the pre-COVID-19 number of incoming complaints.

Fiscal Year	Complaints Received Against Physicians and Surgeons
15/16	8,679
16/17	9,619
17/18	10,888
18/19	11,407
19/20	10,868

Complaints are further discussed in Issue #16 below.

For complaints that are subsequently investigated and meet the necessary legal prerequisites, a Deputy Attorney General (DAG) in the OAG drafts formal charges, known as an "Accusation". An accusation is filed upon signature of the MBC executive director. A hearing before an Administrative Law Judge (ALJ) is subsequently scheduled, at which point settlement negotiations take place between the DAG, the physician and their attorney and MBC staff. Often times these result in a stipulated settlement, similar to a plea bargain in criminal court, where a licensee admits to having violated charges set forth in the accusation, or admits that the MBC could establish a factual and legal basis for the charges in the Accusation at hearing, and accepts penalties for those violations. If a licensee contests charges, the case is heard before an ALJ who subsequently drafts a proposed decision. This decision is reviewed by a panel of MBC members who either adopt the decision as proposed, adopt the decision with a reduced penalty or adopt the decision with an increased penalty. If probation is ordered, a copy of the final decision is referred to MBC's Probation Unit for assignment to an inspector who monitors the licensees for compliance with the terms of probation. Settlements are further discussed in Issue #18 below.

MBC uses its Manual of Model Disciplinary Orders and Disciplinary Guidelines (Disciplinary Guidelines, 16 CCR section 1361) and the Uniform Standards for Substance-Abusing Licensees (Uniform Standards, 16 CCR section 1361.5) as the framework for determining the appropriate penalty for charges filed against a physician. BPC Section 2229 identifies that protection of the public shall be the highest priority for MBC, but also requires that wherever possible, the actions should be calculated to aid in the rehabilitation of the licensee. While the Disciplinary Guidelines and Uniform Standards frame the recommended penalty, the facts of each individual case may support a deviation from the guidelines.

It still takes MBC years to complete the enforcement process and the numbers of cases that do result in disciplinary action are not proportional to the large amount of complaints MBC receives, however, MBC states that it receives a large volume of complaints that are not actionable (e.g. non-jurisdictional or insufficient evidence). The number of disciplinary actions have been relatively stable over the three year period. In FY 2019/20 there was a decrease in the number of default decisions, down to 22 versus 40 in FY 2018/19 and 38 in FY 2017/18. The number of stipulated settlements increased to 323 from 320 in FY 2018/19 and 291 in FY 2017/18. The number of revocations were down in FY 2019/20 when compared to the other two years but no administrative hearings were held from mid-March through the end of the fiscal year, June 30, 2020, due to COVID-19.

MBC's probation unit works to ensure that physicians who are not compliant with probationary orders have swift action taken against their license by either issuing a citation and fine, issuing an order for the individual to cease practicing or referring the matter to OAG for subsequent discipline. MBC's Disciplinary Guidelines were updated to include language allowing MBC to issue a cease practice order for probationers not in compliance with certain terms of their probation.

As review of a case by a medical expert is an important piece of MBC's investigation, MBC works to ensure it successfully recruits these individuals and properly trains the expert reviewer physicians who assist with enforcement. MBC was authorized through the budget to increase the hourly rates for expert reviewers in order to more appropriately recruit and retain these key individuals. MBC offers full day training for expert reviewers, providing an overview of the complaint and field investigation process, legal considerations when providing an opinion, a discussion of real case scenarios to provide an understanding of the difference between extreme and simple departures from the standard of care, report writing and tips to provide effective testimony during a hearing. MBC also works to ensure that ALJs who hear MBC disciplinary actions are trained by MBC on topics of anatomy and systems of the body, prescribing practices, medical record keeping, and co-morbid patients.

MBC issues citations to licensees for technical violations of the Act. MBC reports common reasons for a citation include failing to maintain adequate and accurate medical records, failing to report criminal convictions, failing to report a change of address and aiding and abetting the unlicensed practice of medicine. MBC may also utilize the cite and fine process for dealing with unlicensed practitioners for practicing medicine without a license. MBC reports that it increasingly issues citations for violations identified during the course of an investigation that do not rise to the level to support disciplinary action. In these situations, MBC may require a licensee to complete some education related to a citation, like additional courses in medical record keeping if improper records were the reason a licensee was cited.

Allied Health Professions and Facilities Regulated by MBC

• Licensed Midwives. MBC received regulatory authority over licensed midwives in 1994 and, although other allied health professions later developed their own regulatory boards, MBC continues to have jurisdiction over licensed midwives. A licensed midwife (LM) is an individual who has been issued a license to practice midwifery by MBC. The Midwifery Practice Act, contained in BPC Sections 2505 to 2521 authorizes a licensee to attend cases of normal pregnancy and childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care, for the mother and immediate care for the newborn. LMs can practice in a home, birthing clinic, or hospital environment.

Pathways to licensure for LMs include completion of a three-year postsecondary education program in an accredited school approved by MBC, through a challenge mechanism, or reciprocity through a state with licensing standards that the Board finds as equivalent to its own standards, which currently only includes the states of Florida and Washington. BPC Section 2513(a)-(c) allows a midwifery student and prospective applicant the opportunity to obtain credit by examination for previous midwifery education and clinical experience. Prior to licensure, all midwives must take and pass the North American Registry of Midwives (NARM) examination, adopted by MBC in 1996, which satisfies the written examination requirements set forth in law.

MBC receives guidance on midwifery issues through a Midwifery Advisory Council (MAC). The MAC is made up of LMs (pursuant to BPC 2509, at least half of the MAC members are LMs), a physician, and two non-physician public members.

MBC administers a LM Fund into which LM licensing fees are deposited, and from which MBC received an appropriation in FY 2014/15 to manage the Midwifery Program. LM applicants submit an initial license fee of \$300 and a biennial renewal fee of \$200. This renewal fee accounts for over 80 percent of the LM Fund revenue.

MBC reports that it is meeting its requirement to inform LM applicants within 30 days of receipt of an application as to whether the application is complete and accepted for filing or is deficient and what specific information is required. MBC reports that licensing processing times are consistent with those during the prior sunset review of MBC. MBC follows a process that mirrors that of physician and surgeon licensees in terms of determining the appropriate educational and training qualification (as reflected through materials received directly from entities verifying this information) and also the proper background checks for LM applicants.

MBC approves LM schools and reports that there are currently 11 approved schools. MBC is reviewing how continued approval of schools could be undertaken to ensure approved schools maintain the same standards over time as when they were originally approved by MBC.

MBC reports that disciplinary actions filed against LMs are small, proportionate with the small LM population. According to MBC, there have been 3 actions filed over the past three years and MBC uses its disciplinary guidelines for LMs. MBC promulgated regulations to allow MBC to issue citations and collect fines for unlicensed midwifery activity. LMs are further discussed in Issue #7 below.

Polysomnographic Trainees, Technicians and Technologists. Polysomnography is the
treatment, management, diagnostic testing, control, education and care of patients with sleep
and wake disorders. Polysomnography includes, but is not limited to, the process of analysis,
monitoring, and recording of physiologic data during sleep and wakefulness to assist in the
treatment of disorders, syndromes, and dysfunctions that are sleep-related, manifest during
sleep or disrupt normal sleep activities.

MBC administers a Polysomnographic Program (PP) which registers individuals involved in the treatment, management, diagnostic testing, control, education and care of patients with sleep and wake disorders. The PP registers individuals as polysomnographic trainees, technicians or technologists. Polysomnographic Trainee (Trainee) registration is required for individuals under the direct supervision of a supervising physician, polysomnographic technologist or other licensed health care professionals who provide basic supportive services as part of their education program, including, but not limited to, gathering and verifying patient information, testing preparation and monitoring, documenting routine observations, data acquisition and scoring and assisting with appropriate interventions for patient safety in California. In order to qualify as a Trainee, one must have either a high school diploma or have passed the California General Educational Development Test (GED) and received a California High School Equivalency Certificate. Trainees must also complete at least six months of supervised direct polysomnographic patient care experience or be enrolled in a polysomnographic education program approved by MBC. At the time of application, Trainee applicants must also possess a current certificate in basic life support issued by the American Heart Association.

Polysomnographic Technician (Technician) registration is required for individuals who may perform the services equivalent to that of a Trainee under general supervision and may implement appropriate interventions necessary for patient safety in California. In order to qualify for registration as a Technician, an individual must meet the initial requirements for a Trainee and have at least six months experience at Trainee level.

Polysomnographic Technologist (Technologist) registration is required for individuals who, under the supervision of a physician, are responsible for the treatment, management, diagnostic testing, control, education, and care of patients with sleep and wake disorders in California. Registrants are required to have a valid, current credential as a Technologist issued by the National Board of Registered Polysomnographic Technologists; are required to have graduated from a polysomnographic educational program that has been approved by MBC; and required to have taken and passed the Board of Registered Polysomnographic Technologist examination given by the Board of Registered Polysomnographic Technologists.

MBC reports that the number of PP applicants has remained constant. MBC reports that it is meeting internal goals of applications to the PP within 30 days. As with LMs, MBC follows a process that mirrors that of physician and surgeon licensees in terms of determining the appropriate educational and training qualification (as reflected through materials received directly from entities verifying this information) and also the proper background checks for PP applicants.

According to MBC, there have been 3 disciplinary actions taken over the past three years. Like LMs, MBC promulgated regulations to allow MBC to issue citations and collect fines for unlicensed activity.

• Research Psychoanalysts. A registered research psychoanalyst (RP) is an individual who has graduated from an approved psychoanalytic institution and is registered with MBC. Students currently enrolled in an approved psychoanalytic institution and register with MBC as a Student RP, and as such, are authorized to engage in psychoanalysis under supervision. BPC Sections 2529 and 2529.5 authorize individuals who have graduated from an approved psychoanalytic institute to engage in psychoanalysis as an adjunct to teaching, training, or research and hold themselves out to the public as psychoanalysts and requires these individuals to register with MBC. An RP may engage in psychoanalysis as an adjunct to teaching, training or research. "Adjunct" means that the RP may not render psychoanalytic services on a fee-for-service basis for more than an average of one-third of his or her total professional time,

including time spent in practice, teaching, training or research. Students and graduates are not entitled to state or imply that they are licensed to practice psychology, nor may they hold themselves out by any title or description of services incorporating the words: psychological, psychologist, psychology, psychometrists, psychometrics or psychometry.

As with LMs and those under the PP, MBC follows a process to determine the appropriate educational and training qualification (as reflected through materials received directly from entities verifying this information) and also the proper background checks for applicants for RP registration. Additional information related to the RP registration program can be found in Issue #4 below.

• Medical Assistants. Medical assisting professions have been highlighted as some of the fastest growing employment categories by entities like the United States Bureau of Labor Statistics. Medical assistants (MA) are unlicensed personnel who work in health care practitioner offices and are authorized under BPC Section 2069 to administer medication (only by intradermal, subcutaneous, or intramuscular injections), perform skin tests and perform basic administrative, clerical and technical supportive services when conditions regarding supervision, training, specific authorization and records are met.

A MA must receive training either directly from a physician, surgeon, podiatrist, registered nurse, licensed vocational nurse, physician assistant or a qualified MA. Alternatively, a MA may receive training from a secondary, postsecondary or adult education program in a public school authorized by the Department of Education, in a community college program, or a postsecondary institution accredited by an accreditation agency recognized by the United States Department of Education or approved by the Bureau for Private Postsecondary Education.

While medical assistants are not required to be licensed or register with MBC like other allied health professionals within MBC's jurisdiction, they may be certified by a national certifying body.

MAs can be supervised by physicians, podiatrists or optometrists. Additionally, they may work under the direct supervision of a physician assistant, nurse practitioner or nurse midwife when the supervising physician or surgeon is not on site, only if the physician or surgeon has created a written protocol for the activities of the MA. MAs must receive specific authorization before providing any technical services. This authorization may be in the form of a specific written order or standing order prepared by the supervising physician or podiatrist. The order must include an authorization for the procedure to be performed and it must be noted in the patient's medical record.

MAs are required to document all technical supportive services in the patient's record. In addition, when practicing under the supervision of a physician assistant, nurse practitioner or nurse midwife, the delegation of supervision from the physician or podiatrist to the physician assistant, nurse practitioner or nurse midwife, must be documented in a written standard protocol.

While MBC does not formally oversee MAs as licensees or registrants, the Act specifies that MAs must be at least 18 years old and meet minimum training as outlined in standards established by MBC. MBC does approve certifying organizations that provide certification to medical assistants. According to MBC, there are currently five approved certifying

organizations, two of which are recognized by the National Commission for Certifying Agencies: the American Association of MAs, who provide Certified MA certification the American Medical Technologists who provide Registered MA certification.

Outpatient Surgery Setting Accreditation. Currently, California law prohibits physicians from performing some outpatient surgeries, unless they are performed in an accredited, licensed, or certified setting, specifically outlining that on or after July 1, 1996, no physician shall perform procedures in an outpatient setting using anesthesia, except local anesthesia or peripheral nerve blocks, or both, complying with the community standard of practice, in doses that, when administered, have the probability of placing a patient at risk for loss of the patient's lifepreserving protective reflexes, unless the setting is specified in Health and Safety Code (HSC) section 1248.1. Outpatient surgery settings (OSS) where anxiolytics and analgesics are administered are excluded when these types of anesthesia are administered in compliance with the community standard of practice and in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes. As outlined in HSC section 1248.1, certain OSS are excluded from the accreditation requirement, such as ambulatory surgical centers certified to participate in the Medicare program under Title 18, health facilities licensed as general acute care hospitals, federally operated clinics, facilities on recognized tribal reservations, and facilities used by dentists or physicians in compliance with Article 2.7 or Article 2.8 of Chapter 4 of Division 2 of the BPC.

MBC has adopted standards for accreditation and approving accreditation agencies that perform the accreditation of OSS, ensuring that the certification program includes standards for multiple aspects of the settings' operations. MBC has approved four facility accreditation agencies – the American Association for Accreditation of Ambulatory Surgery Facilities Inc., the Accreditation Association for Ambulatory Health Care, the Joint Commission, and the American Osteopathic Association/Healthcare Facilities Accreditation Program. The Institute for Medical Quality (IMQ) was accredited October 8, 1997, and ceased all accreditation operations effective July 31, 2020. As a result of IMQ's closure, there are approximately 140 OSS that have lost their accredited status. In accordance with HSC section 1248.55(c)(1), these settings are authorized to continue to operate for a period of 12 months in order to seek accreditation through an approved accreditation agency. During the 12-month period, these settings must continue to follow all incident reporting processes as before, and will be reporting directly to MBC until new accreditation is acquired.

MBC posts information regarding OSS on its website, including whether the outpatient setting is accredited or whether the setting's accreditation has been revoked, suspended, or placed on probation, or if the setting has received a reprimand by the accreditation agency.

Approved accrediting agencies are required to notify and update MBC on all outpatient settings that are accredited, or if the accreditation is denied, suspended or revoked. If MBC receives a complaint regarding an accredited OSS, the complaint is referred to the accrediting agency for inspection. Once the inspection report is received, MBC reviews the findings to determine if any deficiencies were identified in categories that relate to patient safety. MBC's enforcement program review patient safety deficiencies and if necessary, refers the matter for formal investigation. Inspection reports must be provided to MBC and posted on the website for public viewing. The lists of deficiencies, plans of correction or requirements for improvements and correction, and corrective action completed are also available to the public.

BPC sections 2216.3 and 2216.4 require an accredited OSS to report adverse events, as defined in HSC section 1279.1 to the Board no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, no later than 24 hours after the adverse event has been detected.

PRIOR SUNSET REVIEW: CHANGES AND IMPROVEMENTS

MBC was last reviewed by the Legislature through sunset review in 2016-2017. During the previous sunset review, 30 issues were raised. In January 2021, MBC submitted its required sunset report to the Senate Committee on Business, Professions and Economic Development and Assembly Committee on Business and Professions (Committees). In this report, MBC described actions it has taken since its prior review to address the recommendations made. The following are some of the more important programmatic and operational changes, enhancements and other important policy decisions or regulatory changes made. For those which were not addressed and which may still be of concern to the Committees, they are addressed and more fully discussed under "Current Sunset Review Issues."

- Changes in Leadership and new Executive Director. In July 2018, Denise Pines became MBC president, focusing on outreach, communication and out-of-the-box thinking, and challenging MBC and its staff to live up to MBC's mission of consumer protection. She facilitated a Consumer Advocate Interested Parties Meeting that brought several consumer advocates, Board members, and staff together. In November 2020, MBC selected Kristina D. Lawson, J.D. to succeed Ms. Pines as president. Ms. Lawson's priorities include extending MBC's ongoing efforts to strengthen the relationships between consumer and patient advocates and the Board. In June 2020, William Prasifka was appointed as executive director of the Board. Mr. Prasifka previously held the position of Chief Executive Officer for the Medical Council of Ireland, which regulates the country's 23,000 physicians.
- Consumer centric efforts. MBC held a first-of-its-kind Consumer Advocate Interested Parties Meeting at the close of its January 2019 quarterly meeting to discuss the enforcement process, share concerns, and collaborate on ways to improve consumer protection. MBC advises that it acquired helpful information from the meeting and worked to implement certain changes, including the posting of information suggested by patient advocates on MBC's website and revising MBC's complaint form.
- Cannabis Guidelines were updated and expanded. MBC updated and expanded its Guidelines for the Recommendation of Cannabis for Medical Purposes which provide guidance and information to physicians and surgeons who choose to recommend cannabis for medical purposes to their patients. This update was done in collaboration with the Center for Medicinal Cannabis Research at the University of California, San Diego, and in accordance with SB 643 (McGuire, Chapter 719, Statutes of 2015).
- <u>Updated publications</u>, <u>website</u>, <u>and social media presence</u>. MBC notes that it modernized the look and feel of its publications with the design of a new seal and logo featuring the Rod of Asclepius which traditionally represents healing and medicinal arts. The layout and design of MBC's Newsletter, one of its main outreach tools, also received a complete redesign using a modern approach. MBC created a column dedicated to consumers in the Newsletter called Consumer Corner. MBC also added a page to its website to track legislation that affects the practice of medicine in California. MBC enhanced its social media profile by launching a Facebook page to use in conjunction with its Twitter page, both of which empower MBC to provide information to stakeholders. MBC increased the number of posts it executes on its Twitter page, boosting the number of Twitter users who follow MBC, and developed an app.

MBC also developed a podcast, "The Medical Board Chat", an innovative way to provide relevant, timely and useful information to its licensees and the public.

- CURES is being used by clinicians and proactively by the Board to ensure proper prescription drug prescribing is occurring. Beginning October 2018, physicians consult CURES prior to prescribing, ordering, administering or furnishing schedule II-IV controlled substances, under specific criteria. To prepare physicians statewide for the change in the law, MBC focused its outreach efforts to various physician groups (hospitals, medical centers, and physician organizations) to provide education regarding the new requirement and to ensure compliance. MBC also established a dedicated CURES page on its website that contains information about CURES including FAQs regarding the mandatory use of CURES, a CURES user guide, an explanation of the law, and information on registration and direct dispensing. MBC worked to review data for incidents in the state where the cause of death for someone was linked to opioids and reviewed records to determine whether prescribing played a role. MBC reviewed approximately 2,700 public death certificates attributable to prescription opioid use and identified 450 patients who may have been inappropriately prescribed to by physicians. While this represents an incredibly small number compared to the number of people who die at the hands of opioids, MBC used a proactive approach to determine whether licensees were connected to any cases. MBC referred 72 cases to other programs that regulate prescribers (such as the Osteopathic Medical Board of California (OMBC) and the Board of Registered Nursing). MBC obtained medical records for the patients and investigated the deaths through its enforcement process. Approximately 23 percent of the cases that MBC opened based on the project, each of which was evaluated by a physician medical expert reviewer to determine whether the case merited further action, resulted in the filing of an accusation, disciplinary action, or action had already been taken against the physician for inappropriate prescribing issues. A second data set for deaths in 2019 was received in November 2020. The information reported 2666 deaths which may have been related to opioids. Thus far, 25 cases have been initiated out of 1422 matters reviewed. A significant number of cases involved street drugs.
- <u>PMBC has clear statutory authority.</u> SB 798 made a number of technical, clarifying changes to make clear that the Doctors of Podiatric Medicine are licensed by the Podiatric Medical Board.
- Notices to consumers are being provided. MBC is in the process of adopting regulations that require licensees to provide notice to their patients that they are licensed by MBC, that patients can check the practitioner's license, and that complaints against the practitioner can be made through MBC's website or by contacting MBC.
- MBC created a Volunteer Physician Registry. In order to facilitate opportunities for physicians to give back to their communities and volunteer their services, the Board launched a Volunteer Physician Registry (VPR) which allows physicians to sign up to volunteer their services in underserved areas statewide. Over 800 physicians have signed up to volunteer their services through the VPR.
- <u>Updated strategic plan.</u> The Board updated its Strategic Plan in 2018.

- <u>Ease of renewal.</u> In support of the statewide effort to go green, and to make the renewal process as efficient as possible, MBC began sending electronic courtesy renewal notices to physicians 180 days prior to the license expiration date. According to MBC, this significantly reduces the number of paper renewal notices mailed and saves on postage costs because physicians and surgeons who renew early will not be mailed a paper renewal form.
- Outreach to medical students continues. MBC recognizes that a significant number of students who attend medical school in California will start their postgraduate training in other states but when MBC staff is present at a teaching hospital affiliated with one of California's medical schools, MBC works to present information and provide advice about the licensing process. This outreach, which includes reviewing applications before they are submitted, providing an explanation of what other training, educational, and criminal history, documents are needed, and more is preventative and helps keep the workload of the MBC's staff consistent while assisting future licensees. MBC reports that with the convenience of having all services provided at an outreach opportunity, physicians enrolled in postgraduate training programs apply earlier in the year and are licensed earlier. This frees up MBC staff to work with applicants whose applications may be deficient, well in advance of deadlines for applying. on remediating deficiencies well in advance of any licensure deadlines and also serves to benefit the teaching hospitals and other health care facilities.

CURRENT SUNSET REVIEW ISSUES

The following are unresolved issues pertaining to MBC or areas of concern that should be considered, along with background information for each issue. There are also recommendations Committee staff have made regarding particular issues or problem areas MBC needs to address. MBC and other interested parties have been provided with this Background Paper and MBC will respond to the issues presented and the recommendations of staff.

MBC ADMINISTRATION ISSUES

<u>ISSUE #1:</u> (BOARD COMPOSITION.) Does MBC's composition need to be updated to include additional members of the public?

Background: In 2010, the Federal Trade Commission (FTC) brought an administrative complaint against the North Carolina State Board of Dental Examiners (Board) for exclusion of non-dentists from the practice of teeth whitening. The FTC alleged that the Board's decision was an uncompetitive and unfair method of competition under the Federal Trade Commission Act. This opened the Board to lawsuits and substantial damages from affected parties.

The Board was composed of 6 licensed, practicing dentists and 2 public members. The practice of teeth whitening was not addressed in the statutes comprising the Dental Practice Act. Instead of initiating a rulemaking effort to clarify the appropriate practice of teeth whitening, the Board sent cease-and-desist letters to non-dentists in the state offering teeth whitening services. The Board argued that the FTC's complaint was invalid because the Board was acting as an agent of North Carolina, and according to state-action immunity, one cannot sue the state acting in its sovereign capacity for anticompetitive conduct. A federal appeals court sided with the FTC, and the Board appealed to the United States Supreme Court (Court).

In February 2015, the Court agreed with the FTC and determined that the Board was not acting as a state agent and could be sued for its actions. The Court ruled, "Because a controlling number of the Board's decision-makers are active participants in the occupation the Board regulates, the Board can invoke state-action antitrust immunity only if it was subject to active supervision by the State, and here that requirement is not met."

The Court was not specific about what may constitute "active participants" or "active supervision." However, the Court did say that "active supervision" requires "that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy," and that "the supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it."

In October 2015, the FTC released a staff guidance, *Active Supervision of State Regulatory Boards Controlled by Market Participants* in order to better explain when active supervision of a state regulatory board would be required, in order for a board to invoke the state action defense. The guidance also aimed to highlight what factors are relevant when determining if the active supervision requirement has been satisfied. The FTC states that active supervision includes the ability of a state supervisor to review the substance of the anticompetitive decision and have the power to veto or modify a decision. The state supervisor may not be an active market participant. In addition, the FTC states that active supervision must precede the implementation of the alleged anticompetitive restraint.

The FTC states that the guidance addresses only the active supervision requirement of the state action defense, and antitrust analysis is fact-specific and context-dependent. This means that although a state action defense might not be applicable in a certain case, this does not mean that the conduct of a regulatory board necessarily violates federal antitrust laws.

On October 22, 2015, the Committees held a joint informational hearing to explore the implications of the Court decision on the DCA's professional regulatory boards and consider recommendations.

In response to the Court's decision, State Senator Jerry Hill requested an opinion from the Office of Attorney General Kamala Harris (AG). The AG released the following:

"North Carolina Dental has brought both the composition of licensing boards and the concept of active state supervision into the public spotlight, but the standard it imposes is flexible and context-specific. This leaves the state with many variables to consider in deciding how to responds.

"Whatever the chosen response may be, the state can be assured that North Carolina Dental's 'active state supervision' requirement is satisfied when a non-market-participant state official has and exercises the power to substantively review a board's action and determines whether the action effectuates the state's regulatory policies."

Boards like MBC are semiautonomous bodies whose members are appointed by the Governor and the Legislature. Although most of the non-healing arts boards have statutory authority for a public majority allotment in their makeup, most healing arts and non-healing arts boards are comprised of a majority of members representing the profession.

North Carolina State Board of Dental Examiners v. FTC placed limitations on the immunity of regulatory boards controlled by active market participants. This is because individuals who are directly affected by their own rulemaking may not be able to detect their biases, purposefully or inadvertently placing their benefit over those of the public. Or, as the Supreme Court stated, "Dual allegiances are not always apparent to an actor."

Although the boards are tied to the state through various structural and statutory oversights, it is presently unclear whether current laws and practices are sufficient to ensure that the boards are state actors and, thus, immune from legal action. Changing MBC's composition to a public member majority may decrease MBC's risk of exposure to lawsuits and may have the added value of creating a more patient centric program. Particularly given the public member vacancies MBC currently has, it may be helpful for the Committees to understand what impacts a change in composition could have.

<u>Staff Recommendation:</u> The Committees may wish to amend the Act to add two additional members of the public to MBC, one appointed by the Senate Committee on Rules, and one appointed by the Speaker of the Assembly, to establish a public majority membership.

ISSUE #2: (REGULATIONS.) What is the current timeframe for MBC regulatory packages to be approved and finalized?

Background: Promulgating regulations is at the heart of MBC's work to implement the law and establish a framework for consumer protection. According to the Office of Administrative Law (OAL), a "regulation" is any rule, regulation, order or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it. When adopting regulations, every department, division, office, officer, bureau, board or commission in the executive branch of the California state government must follow the rulemaking procedures in the Administrative Procedure Act (APA) (Government Code section 11340 et seq.) and regulations adopted by OAL, unless expressly exempted by statute from some or all of these requirements. The APA requirements are designed to provide the public with a meaningful opportunity to participate in the adoption of regulations or rules that have the force of law by California state agencies and to ensure the creation of an adequate record for the OAL and judicial review.

The rulemaking process does provide some discretion to agencies. While each agency must comply with timeframe requirements and must produce the same uniform documents supporting rulemaking efforts to submit to OAL, there are not the same standards for how regulation packages are determined, written, and produced.

Prior to 2016, boards and bureaus like MBC that are organized within DCA filed rulemaking packages directly with OAL. Boards and bureaus were not required to submit rulemaking packages to DCA or the overseeing agency for review and approval prior to submission for publication in the Notice Register. OAL reported that this process was unusual within state government: most programs must submit regulations packages to their respective agency for approval. As a result, in September 2016, the Secretary of the Business, Consumer Services and Housing Agency (BCSH) changed the procedures: boards and bureaus were now required to submit rulemaking packages to the department and BCSH for review prior to filing with OAL. BCSH stated that the reason for the decision was an increase in the number of regulations disapproved by OAL for failing to meet their statutory requirements.

According to a 2019 DCA report to the Legislature, Internal Review of Regulation Procedures, "the resulting enhanced scrutiny from Agency and DCA's Legal Affairs Division successfully reduced the number of disapproved regulation packages, with the number of disapprovals falling from nine in 2016 to only one in 2018." The report also found that "while disapproval rates plummeted, a consequence was lengthened timelines to adopt regulations. Several boards and bureaus raised objections to the lengthened review time and reported difficulty obtaining timely updates about regulation packages under review." The "pre-review" process required regulations to go through DCA's entire review process prior to the package being submitted for public comment. DCA established a formal Regulations Unit to "minimize the length of time it currently takes to review regulatory packages; allow board and bureau attorneys to focus on the increased workload of non-regulatory work; respond to the demand of regulation packages under review and the increase of regulation packages from AB 2138 (Chiu and Low; Chapter 995, Statutes of 2018); avoid the habitual carry-over of regulation packages; and, enhance the level of regulation training provided to boards and bureaus to improve the quality of regulations and create efficiencies by having better quality packages submitted for review."

MBC has its own Staff Counsel. It would be helpful for the Committees to have a better understanding of the status of necessary MBC regulations, the timeframe for regulations to be processed and complete and what efficiencies MBC has realized since the creation of the Regulations Unit.

<u>Staff Recommendation:</u> MBC should provide the Committees with an update on pending regulations and the current timeframes for regulatory packages. In addition, the MBC should inform the Committees of any achieved efficiencies in promulgating regulations in recent years.

ISSUE #3: (DATA SHARING.) Data collected by other state agencies impacts MBC's knowledge of its licensee population. MBC is supposed to receive data from a number of state agencies yet does not always receive the information necessary for MBC to do its job. What is the status of MBC's efforts to obtain important data from other state agencies?

<u>Background:</u> Various state agencies collect and receive health related data that may be connected to activities of MBC licensees. For example, the Department of Public Health (DPH) Office of Vital Records maintains certificates for vital events in California, including death certificates. The Department of Health Care Services (DHCS) and Department of Social Services (DSS) work together to track psychotropic medication prescription data for children in foster care. DPH's Laboratory Field Services program is supposed to inspect and subsequently track information related to the outcome of inspections of laboratories. In each of these instances, MBC's work may be improved by having access to data from other agencies. For example, MBC can gauge prescribing trends for certain populations and conditions with timely access to psychotropic medication prescriptions for foster youth. With data, MBC can both set guidelines and advise on best practices as well as take enforcement action when necessary in events of demonstrated prescribing problems.

MBC in being informed about licensees who may be violating the law or to help MBC be a better regulator by monitoring trends. MBC has a long-standing agreement with DPH to receive death certificate information on deceased physicians on an ongoing basis in order to update physician license records. MBC also entered into a data use agreement with the DPH to receive information from death certificates when the death was related to opioids. Long faced with calls to do more about rising deaths stemming from prescription drug use, abuse, and overdose, MBC received data for 2012 and 2013 which indicated 2,694 deaths during that two year period. This resulted in 520 investigations of 471 prescribers. As of October 1, 2020, 75 accusations were filed against 66 physicians, a fraction of total MBC licensees. To date, there have been 11 license surrenders, 20 probation terms, and 21 letters of public reprimand. In 5 cases the physician's license was already revoked.

MBC entered into a DUA with DHCS and DSS to receive information about licensees who had prescribed three or more psychotropic medications to foster youth for 90 days or more during July 1, 2014 to December 31, 2014. This DUA was codified in statute (SB 1174, McGuire, Statutes of 2016) and the data is now required to be provided to MBC on an ongoing basis for ten years. MBC previously reported that through a review of the data received from DHCS and DSS for the 2014 time frame, MBC identified numerous patients who may have been inappropriately prescribed psychotropic medications.

In addition to these agreements, there are other state agencies and other data that could be obtained to assist the MBC in doing its job. DHCS Audits and Investigations Unit (AIU) performs billing audits and may identify physicians and surgeons who may be violating the law. Similarly, DPH audits hospitals and other facilities and during an audit may obtain information regarding a physician who

may be in violation of the law. Or DPH, through its review of laboratories, may identify a physician who is receiving inducements. While MBC may receive some referrals from DPH, there is no requirement to provide this information to MBC, potentially preventing MBC from having important information about licensees to determine whether they are violating the Act.

<u>Staff Recommendation:</u> MBC should inform the Committees on the status of DUAs and whether information is being properly shared across agencies, particularly information that could allow MBC to determine whether its enforcement actions are appropriate, necessary, or require updates based on trends gauged through data.

ISSUE #4: (RESEARCH PSYCHOANALYST REGISTRATION.) As noted previously, MBC registers Research Psychoanalysts (RPs), individuals who practice psychoanalysis for fees for no more than one third of the individual's total professional time (which includes time spent in practice, teaching, training or research). Why does MBC administer the RP registration program rather than the Board of Psychology which oversees those practicing in psychology and has experience administering registration programs?

Background: According to the American Psychological Association (APA), psychoanalysis is a specialty in psychology that is distinguished from other specialties by its body of knowledge and its intensive treatment approaches. It aims at structural changes and modifications of a person's personality. Psychoanalysis promotes awareness of unconscious, maladaptive and habitually recurrent patterns of emotion and behavior, allowing previously unconscious aspects of the self to become integrated and promoting optimal functioning, healing and creative expression. The APA states that psychoanalytic training typically requires four to eight years of advanced study after completion of a doctoral degree in psychology acceptable to the American Board of Professional Psychology and further requires specialized training at free-standing psychoanalytic institutes, postdoctoral university programs, or an equivalent training secured independently that is acceptable to the American Board and Academy of Psychoanalysis.

A registered RP is an individual who has graduated from an approved psychoanalytic institution and is registered with MBC. Students currently enrolled in an approved psychoanalytic institution and register with MBC as a Student RP, and as such, are authorized to engage in psychoanalysis under supervision. Existing law authorizes individuals who have graduated from an approved psychoanalytic institute to engage in psychoanalysis as an adjunct to teaching, training, or research and hold themselves out to the public as psychoanalysts. "Adjunct" means that the RP may not render psychoanalytic services on a fee-for-service basis for more than an average of one-third of his or her total professional time, including time spent in practice, teaching, training or research. Students and graduates are not entitled to state or imply that they are licensed to practice psychology, nor may they hold themselves out by any title or description of services incorporating the words: psychological, psychologist, psychology, psychometrists, psychometrics, or psychometry. MBC follows a process to determine the appropriate education and training qualification (as reflected through materials received directly from entities verifying this information) and the proper background checks for applicants for RP registration.

	Registration Population							
			FY 2016/2017	FY 2017/2018	FY 2018/2019	FY 2019/2020		
8003		Active	94	86	90	82		
	8003 – Research Psychoanalyst	Delinquent	14	24	15	2:		
	8003 – Research Esychoanaryst	Out of State	Unknown	Unknown	Unknown			
		Out of Country	Unknown	Unknown	Unknown			

In 1977, when RPs were first recognized statutorily, MBC—then the Board of Medical Quality Assurance—was comprised of three sections: the Division of Medical Quality, the Division of Licensing, and the Division of Allied Health Professions. Several allied health professions were within the jurisdiction of the Division of Allied Health Professions, including audiologists, acupuncturists, hearing aid dispensers, physical therapists, medical assistants, physician assistants, podiatrists, registered dispensing opticians, speech pathologists, and psychologists. In 1990, when the Board of Psychology came into existence, RPs remained under the MBC's oversight.

The Board of Psychology previously had a member who served as president of the Northern California Society for the Psychoanalytic Psychology Board of Directors and who was an assistant editor for a psychoanalytics publication. It appears that the Board of Psychology may have more expertise in this discipline and may be a more appropriate entity to register RPs who engage in the practice.

<u>Staff Recommendation:</u> In coordination with the Board of Psychology, MBC should advise the Committees as to why RPs are under the jurisdiction of the MBC rather than the Board of Psychology. The Committees may wish to transfer registration of RPs to the Board of Psychology, which already successfully administers registration programs for individuals practicing psychology.

<u>ISSUE #5:</u> (PHYSICIAN HEALTH AND WELLNESS PROGRAM.) MBC is implementing a Physician Health and Wellness Program. MBC's prior program faced significant shortfalls and raised concerns about patient protection. How will MBC ensure the program will successfully assist physicians while ensuring there is no harm to patients?

<u>Background:</u> SB 1177 (Galgiani, Chapter 591, Statutes of 2016) authorized MBC to establish a Physician and Surgeon Health and Wellness Program (PHWP) for the early identification and appropriate interventions to support a licensee in their rehabilitation from substance abuse and authorizes MBC to contract with an independent entity to administer the PHWP. The bill required MBC, if it establishes a PHWP, to contract for administration with an independent administering entity selected by MBC through a request for proposals process. MBC previously noted that it anticipated having all of the necessary activities completed so a program could start in the fall of 2018.

SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) required the DCA to develop uniform and specific standards that shall be used by each healing arts board in dealing with substance-abusing licensees in 16 specified areas, including requirements and standards for: (1) clinical and diagnostic evaluation of the licensee; (2) temporary removal of the licensee from practice; (3) communication with licensee's employer about licensee status and condition; (4) testing and frequency of testing while participating in a diversion program or while on probation; (5) group meeting attendance and qualifications for facilitators; (6) determining what type of treatment is necessary; (7) worksite monitoring; (8) procedures to be followed if a licensee tests positive for a banned substance; (9) procedures to be followed when a licensee is confirmed to have ingested a banned substance;

(10) consequences for major violations and minor violations of the standards and requirements; (11) return to practice on a full-time basis; (12) reinstatement of a health practitioner's license; (13) use and reliance on a private-sector vendor that provides diversion services; (14) the extent to which participation in a diversion program shall be kept confidential; (15) audits of a private-sector vendor's performance and adherence to the uniform standards and requirements; and (16) measurable criteria and standards to determine how effective diversion programs are in protecting patients and in assisting licensees in recovering from substance abuse in the long term. The Uniform Substance Abuse Standards (Uniform Standards) were finally adopted in early 2010, with the exception of the frequency of drug testing which was finalized in March 2011. MBC formally implemented the Uniform Standards in July 2015.

MBC notes that draft regulations for the PHWP were submitted to DCA for review in April 2018. Following the submission of the draft regulations to DCA, the DCA Substance Abuse Coordination Committee (SACC) met as required by SB 796 (Hill, Chapter 600, Statutes of 2017) and approved some changes to the Uniform Standards. The SACC has not yet officially incorporated and disseminated the revised Uniform Standards, but this development, along with other factors, caused MBC staff to reconsider the format of the draft PHWP regulations. When the SACC formally changes the Uniform Standards, MBC will be required to go through the rulemaking process to amend its own Uniform Standards set forth its regulations. If the requirements were repeated in both MBC's Uniform Standards and the PHWP regulations, then changes to multiple regulatory sections would likely be necessary every time the SACC changed the Uniform Standards, thereby causing inefficiency. MBC is in the process of sending amended draft regulations to DCA.

MBC advises that this program is very different than the prior Diversion Program. Physicians will not be able to divert from the disciplinary process by entering and successfully completing this program. In addition, the program will have to comply with regulations that are based upon the law, as well as the Uniform Standards. These regulations are going to follow the Uniform Standards adopted by MBC in 2015, which in most circumstances do not allow for deviations. The program will also be run by a third-party entity, not MBC staff, and will have more expertise and not be subject to civil service requirements. MBC will be able to have an independent auditor review the program at least every three years, which in turn will provide MBC with information about program compliance with the regulations and Uniform Standards. Lastly, the program will provide updates MBC on the status of individuals in the program.

<u>Staff Recommendation:</u> MBC should update the Committees on the implementation of a PHWP, including the current status of regulations.

<u>ISSUE #6:</u> (MENTAL HEALTH SERVICES FOR COVID-19 PROVIDERS.) Under ordinary circumstances, frontline healthcare providers and first responders often face difficult situations that are mentally and emotionally challenging. Are there new issues arising from, or ongoing issues being worsened by, the extreme conditions of the COVID-19 pandemic?

<u>Background:</u> Throughout the COVID-19 pandemic, frontline healthcare workers and first responders, such as physicians, nurses, respiratory care therapists, paramedics, and more, have been caring for COVID-19 patients through multiple deadly surges, including a record-shattering death toll surge in December of 2020.

The Centers for Disease Control notes that "[p]roviding care to others during the COVID-19 pandemic can lead to stress, anxiety, fear, and other strong emotions.... Experiencing or witnessing life-

threatening or traumatic events impacts everyone differently. In some circumstances, the distress can be managed successfully to reduce associated negative health and behavioral outcomes. In other cases, some people may experience clinically significant distress or impairment, such as acute stress disorder, post-traumatic stress disorder (PTSD), or secondary traumatic stress (also known as vicarious traumatization). Compassion fatigue and burnout may also result from chronic workplace stress and exposure to traumatic events during the COVID-19 pandemic."

Frontline healthcare workers are essential to the state of California. Given the length and the unique conditions of the COVID-19 pandemic, it may be beneficial to track trends and identify potential challenges and solutions in delivering mental health care and support for frontline healthcare workers who have been under extreme physical and mental pressure since the start of the coronavirus pandemic.

<u>Staff Recommendation:</u> *MBC* should discuss any findings related to the mental and behavioral healthcare needs of frontline healthcare providers arising from the COVID-19 pandemic.

<u>ISSUE #7:</u> (LICENSED MIDWIVES.) MBC regulates licensed midwives but regulations to allow LMs to practice independently have stalled. What is the status of LM independent practice authority and what changes may be necessary to achieve the Legislature's intent?

<u>Background:</u> MBC received regulatory authority over licensed midwives in 1994. A licensed midwife (LM) is an individual who has been issued a license to practice midwifery by MBC. LMs who have achieved the required educational and clinical experience in midwifery (including completing a three-year postsecondary education program in an accredited midwifery school approved by the MBC) or met the challenge requirements (obtaining credit by examination for previous education and clinical experience – as of January 1, 2015, new LMs may not substitute clinical experience for formal didactic education), must pass the North American Registry of Midwives' comprehensive examination. After successful completion of this examination, prospective applicants are designated as a "certified professional midwife" and are eligible to submit an application for licensure as an LM.

LMs are authorized to attend cases of normal pregnancy and childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care, for the mother and immediate care for the newborn. LMs can also directly obtain supplies and devices, obtain and administer drugs and diagnostic tests, order testing and receive reports that are necessary to his or her practice of midwifery and consistent with his or her scope of practice. LMs can practice in a home, birthing clinic or hospital environment. As of March 1, 2021 there are 471 actively licensed LMs in California.

When the Licensed Midwifery Practice Act of 1993 was first enacted, LMs were required to practice under the supervision of physicians. Since AB 1308 (Bonilla, Chapter 665, Statutes 2013) went into effect on January 1, 2014, LMs are authorized in statute to practice autonomously without any supervision requirements.

LMs do not have member representation on MBC, rather, BPC Section 2509 authorizes MBC to create a Midwifery Advisory Council (MAC) and appoint its members consisting of LMs and members of the public, specifically at least half of the MAC members are LMs, and it includes one physician and two public members. The MAC makes recommendations on matters specified by MBC and MBC holds all authority to take action regarding the licensure and regulation of midwives in California.

AB 1308 removed the statutory requirement for an LM to practice under the supervision of a M.D. and instead specified that a midwife may assist in "normal" pregnancy and birth, defined through regulations. Until MBC adopts regulations, LMs are not able to be a "comprehensive perinatal provider" for purposes of providing comprehensive perinatal services to Medi-Cal beneficiaries in the Comprehensive Perinatal Services Program (CPSP). SB 407 (Morrell, Chapter 313, Statutes of 2015) authorized a health care provider to employ or contract with licensed midwives for the purpose of providing comprehensive perinatal services in the CPSP.

MBC held several interested parties meetings on the regulations to implement AB 1308, including working with both the California Association of Midwives/California Association of Licensed Midwives (CAM/CALM) and the American College of Obstetricians and Gynecologists. A sticking point in the discussions on regulations was whether prior cesarean sections should be on the list of preexisting conditions which would require a physician and surgeon examination prior to the LM continuing to provide care.

MBC established a Midwifery Task Force, comprised of two MBC members to assist with the development of regulations pursuant to AB 1308. The Midwifery Task Force discussed the challenges created by the current language under 2507(b)(2) requiring a LM to refer a client with a preexisting maternal disease or condition likely to affect the pregnancy, or a significant disease arising from the pregnancy, to a physician for an examination and a determination by the physician that the risk factors presented by the individual's disease or condition are not likely to significantly affect the course of pregnancy and childbirth if the LM is allowed to continue care. The Task Force was informed that requiring physicians to make this determination puts physicians in a difficult position, causing reluctance and challenges for collaboration and access to care for midwifery clients. It was acknowledged that this issue could not be resolved through regulations.

The Midwifery Task Force determined that legislation was necessary. Under the proposal, it would be the LM making that determination within the midwifery standard of care, rather than the physician and surgeon, as to whether the individual should continue with midwifery care. If the individual does have a preexisting maternal disease or condition likely to affect the pregnancy, or a significant disease arising from the pregnancy likely to significantly affect the course of pregnancy or childbirth, the LM would have to refer the individual to a physician and surgeon for care, with the LM providing collaborative care, as appropriate.

MBC approved pursuing the proposed statutory amendment to change the requirements under BPC section 2507 so that if the client has a preexisting maternal disease or condition likely to affect the pregnancy, or a significant disease arising from the pregnancy, the midwife will still be required to refer the client to a physician trained in obstetrics for an assessment of the risk factors that may adversely affect the outcome of the pregnancy or childbirth. The midwife would have to include the physician's assessment in evaluating whether the client's disease or condition is likely to significantly affect the course of the pregnancy or childbirth. It would ultimately be the midwife making the determination within the midwifery standard of care, rather than the physician, as to whether the client should continue with midwifery care. The proposed language was not included in MBC's prior sunset bill in 2017 and there have been no statutory changes since then.

MBC reports that at its quarterly meeting on November 7, 2019, MBC considered and rejected a legislative proposal to prohibit LMs from attending home births if the mother has had a prior cesarean delivery.

Members of the MAC, individual LMs, and state midwifery professional associations have called for LMs to be regulated by a separate board within the DCA. In general, these stakeholders argue that LMs and the physician community have incompatible approaches to providing care, therefore, it is inappropriate for LMs to be regulated by MBC. MBC notes in its sunset report that it agrees and that with an appropriate scope of practice and related statutory protections for consumers, LMs could be effectively regulated through a separate entity within DCA.

In support of this proposal, CALM writes that:

"as physicians and surgeons, Board members are not trained or educated in midwifery practice, nor are they taught about the midwifery profession when they join the Board...Board members are often unaware that they are responsible for regulating LMs; that LM clinical practice takes place in out-of-hospital, community-based settings; that LMs are not nurses or nurse-midwives; that LMs do not engage in the practice of medicine; and that the midwifery model and standards of maternity care are distinct from the obstetrical model of maternity care. The Board routinely assigns physicians with no background in midwifery education, training, or scope of practice to serve as expert reviewers of LM complaints and investigations and to determine the outcome of LM disciplinary cases. Physician expert reviewers assigned to LM cases rely on guidelines provided by the Board that have with no statutory authority and have not been promulgated...The Board refers all hospital transport reports, which are meant for data collection and represent adherence to appropriate standards of care, to the Enforcement Program for review as potential complaints...Board members' general lack of awareness of or interest in the licensed midwife profession is reflected in the notable absence of information or programs for or about LMs found in the outreach and communication initiatives of the Board's Office of Public Affairs. Board initiatives on professional development and quality improvement are likewise focused almost exclusively on physicians. The Board has not appropriately updated LM guidelines and regulations as standards of care evolve and new evidence and research becomes available. The Board has claimed that rules cannot be promulgated when stakeholders are in disagreement; however, its insistence that physician associations with interests in direct conflict with LMs be treated as stakeholders has resulted in regulatory capture. The Board's billing practices create inefficiencies that disproportionately impact LMs when it comes to shared costs...

[The] MAC cannot function effectively or efficiently because it must receive prior approval from the Board for topics or concerns, which may only be considered at subsequent meetings; Midwifery Task Force members, like other members of the Board, are not trained in midwifery and are not adequately familiar with LM standards of care and regulation...

While the Board's exercise of its statutory jurisdiction over LMs is a relatively minor aspect of its workload, for CALM and the families we serve, control over midwifery practice by another profession remains an ongoing challenge that is becoming increasingly unsustainable."

<u>Staff Recommendation:</u> MBC should describe the impacts of creating a new, standalone board for a small licensing population, including costs that would be necessary to establish a LM board. MBC should inform the Committees of the benefit to patients that this proposal would result in.

MBC BUDGET ISSUES

ISSUE #8: (COST RECOVERY.) Current law prohibits MBC from seeking reimbursement from physicians for costs related to disciplinary action. This provision only applies to physicians and MBC still has the ability to seek cost recovery for other allied health professionals it may take disciplinary action against. In general, DCA boards are authorized to collect payment from licensees for the high costs a board pays related to disciplinary action, as investigation and prosecution charges significantly affect both fund conditions and case adjuducation. Should MBC once again be authorized to seek cost recovery from physicians for disciplinary action?

Background: MBC has been prohibited from recovering costs for administrative prosecution of physicians since 2006 when SB 231 (Figueroa, Chapter 674, Statutes of 2005) went into effect. Specifically, BPC Section 125.3 (k) states that MBC "shall not request nor obtain from a licentiate, investigation and prosecution costs for a disciplinary proceeding against the licentiate. The board shall ensure that this subdivision is revenue neutral with regard to it and that any loss of revenue or increase in costs resulting from this subdivision is offset by an increase in the amount of the initial license fee and the biennial renewal fee, as provided in subdivision (e) of Section 2435."

In 2006, when MBC's ability to obtain cost recovery was eliminated, the Board was able to adopt regulations to increase the physician and surgeon fee to make this elimination cost neutral. At that time, MBC determined that the renewal fee would be increased by \$15 to recuperate the funds that were eliminated due to cost recovery. This \$15 fee increase was not based on what MBC spent, nor was it based upon the amount that had been ordered. It was based on what MBC had received in cost recovery each year for the prior three fiscal years. As a result of the fee increase, the elimination of cost recovery did not initially impact MBC's budget. However, since 2006, the Board's budget has increased from 42 million to 62 million dollars, and as such, the current \$15 fee is not commensurate with what MBC would have received in cost recovery if it had the authority to collect those monies.

MBC advises that the inability to receive cost recovery has not impacted case outcomes. While it was anticipated that more cases would go to hearing with the elimination of cost recovery, MBC still settles 70-80 percent of its cases, thus the inability to recover costs has no impact on whether MBC determines to settle a case or not. MBC continues to review the violations the physician committed, reviews the disciplinary guidelines, and on a case-by-case basis, offers a settlement that ensures consumer protection and rehabilitation of the physician. MBC states that it does not resist going to hearing based upon potential costs, however, not having cost recovery as an option impacts MBC's ability to resolve cases expeditiously. Enabling MBC to seek cost recovery may help offset the costs of investigations through either recouping a portion of those costs or by providing incentive for an accused physician to settle their case, thereby avoiding the costs associated with an ALJ hearing.

With OAG costs rising and charges higher for OAG efforts today than in 2005, it would be helpful for the Committees to determine whether MBC still has the ability to pay for, without the option of reimbursement, disciplinary action. It would be helpful for the Committees to see a breakdown of charges for an average case that results in disciplinary action. It would be helpful for the Committees to better understand the impact of this inability to recover costs on MBC's fund and significantly, whether the inability to recover costs drives MBC's and OAG's decision to settle certain cases that would otherwise continue to accrue costs.

<u>Staff Recommendation:</u> The Committees may wish to again provide MBC with cost recovery authority.

ISSUE #9: (FUND CONDITION AND FEES.) MBC has not updated fees for 12 years and is now facing insolvency. Should fees be raised? Should minimum fee amounts be established in the Act?

<u>Background:</u> MBC does not receive funding from the state's General Fund. Expenses are supported entirely by fees paid by MBC applicants and licensees. MBC's revenue has not kept up with its growing expenditures, drawing MBC's reserves down to extremely low levels.

MBC's fee structure has been unchanged since 2009, when the initial licensure and renewal licensure fees for physicians and surgeons were reduced from \$805 to \$783. This reduction was due to the discontinuation of the Diversion Program. MBC fees for its other regulated professions (LMs, polysomnography technicians, and RPs) have not changed since their inception.

MBC states that it has continued to see a significant increase in the workload for its licensing and enforcement programs. Specifically, MBC reports the following workload increases from FY 2006/07 to FY 2018/19:

- 28 percent in Physician and Surgeon applications,
- 57 percent in Physician and Surgeon complaints,
- 31 percent in Physician and Surgeon investigations opened, and
- 54 percent of Physician and Surgeon investigations referred to the OAG.

In particular, expenditures related to the OAG have been a significant cost driver for MBC, having increased 35.3 percent (\$4M) from FY 2006/07 to FY 2018/19 (\$15.2M). For example, between FY 2016/17 through FY 2018/19 the OAG exceeded their budget allocation by \$1.7M, resulting in MBC having to absorb these costs.

MBC also projects certain future increases to its expenditures, including:

- In FY 2019/20 the Board's AGO's budget allocation increased 41.0 percent (\$4.9M) from \$12M to \$16.9M in FY 2020/21 due to the increased OAG's hourly rate. From FY 2020/21 to FY 2024/25 the projected budget is expected to increase an additional 23.1 percent from \$16.9M to \$20.8M.
- HQIU staff salary and benefits expenditures are expected to increase by 44.3 percent from \$19.6M in FY 2018/19 to \$28.3M in FY 2024/25. This is based on an annual average increase of approximately 6.3 percent.
- Between FY 2018/19 and FY 2024/25 the Board's Personnel Services costs including salary and benefits are projected to increase by 59 percent from \$15.0M to \$23.8M. This is based on an annual average increase of approximately 9.8 percent.
- OAH costs are projected to increase 69 percent from FY 2018/19 (\$1.6M) to \$2.7M in FY 2024/25. This is based on an annual average increase of approximately 11.5 percent.

- DCA Pro Rata is projected to increase from \$5.1M in FY 2018/19 to \$6.7M in FY 2024/25, which equates to an average of 4.5 percent each year.
- Evidence/witness costs are projected to increase from \$2.3M in FY 2018/19 to \$2.8M in FY 2024/25 which equates to an average of 3.1 percent each year.

In November 2019, MBC contracted with CPS HR Consulting to perform a fee study to determine the appropriate levels for licensing fees for MBC to conduct its business at a service level that is efficient for licensees and ensures public protection. The fees reviewed in the study include Physician and Surgeon, Special Faculty, LM, Polysomnographic Trainee/Technician/Technologist, RP, and Fictitious Name Permit fees. The final report, *Medical Board of California: Fee Study*, published January 2020 notes that MBC's revenue has remained relatively static in the past 13 fiscal years, growing from \$49.7 million in FY 2006/07 to \$59.6 million in FY 2018/19, representing an increase of 19.9 percent. This calculates to an annual growth of 1.5 percent. During the same period, expenditures have outpaced revenues and total expenditures have grown from \$44 million in FY 2006/07 to \$65.9 million in FY 2018/19 for an overall increase of 49.8% and an annual growth of 3.8 percent. According to the report, MBC's fund is structurally imbalanced and is estimated to have a fund balance of \$0.6 million (0.08 months-in-reserve) by the end of FY 2020/21 and will be insolvent by the beginning of FY 2021/22. The report notes that if MBC incurs any additional unbudgeted cost increases or seeks any additional resources beyond what is currently authorized, the fund reserve will drop even further.

The report recommends that, to prevent insolvency and to achieve a mandatory reserve as required by statute, MBC should seek the statutory fee increases below to accommodate the expenditures. The report also recommends that MBC should increase the reserve to four months.

Fee Type	Current Fee	Adjusted Fee	Percent Increase	Increase amount
Physician/Surgeon Application	\$442	\$625	+41%	\$183
Physician/Surgeon Initial Licensure	\$783	\$1150	+47%	\$367
Physician/Surgeon Renewal	\$783	\$1150	+47%	\$367
Research Psychoanalyst Initial App + License	\$100	\$150	+50%	\$50
Research Psychoanalyst Renewal	\$50	\$75	+50%	\$25
Polysomnography Application (Trainee, Technician, Technologist)	\$100	\$120	+20%	\$20
Polysomnography Initial Registration (Trainee, Technician, Technologist)	\$100	\$120	+20%	\$20
Polysomnography Renewal (Trainee, Technician, Technologist)	\$150	\$220	+47%	\$70
Midwife Initial	\$300	\$450	+50%	\$150
Midwife Renewal	\$200	\$300	+50%	\$100
Special Faculty Permit Application	\$442	\$442	0%	0
Special Faculty Permit Initial Licensure	\$783	\$783	0%	0
Special Faculty Permit Renewal	\$783	\$1150	+47%	\$367
Fictitious Name Permit Initial	\$50	\$70	+40%	\$20
Fictitious Name Permit Renewal	\$40	\$50	+25%	\$10
Fictitious Name Duplicate Certificate	\$30	\$40	+33%	\$10

MBC agrees with setting minimum amounts for its various fees in statute at the levels recommended in the report. MBC also requests authority to increase those amounts by up to an additional 10 percent,

and decrease them through the rulemaking process if MBC reaches its maximum reserve amount. With regards to the statutorily required four month reserve limit, MBC believes this inhibits MBC's ability to manage revenue shortfalls. MBC notes that other DCA programs do not have a cap specific to their reserve funds or one that is higher than MBC's, and adds that the programs without a cap specific to their respective practice act are bound by BPC section 128.5, which generally requires all DCA boards and bureaus to lower fees when the fund has an unencumbered balance equal to or greater than the board's operating budget for the following two years. To address future revenue shortfalls and unanticipated expenses, the Board believes the two-to-four month reserve requirement should be repealed, therefore authorizing it to maintain a reserve balance of up to two years of unencumbered expenses.

MBC also notes that it should be authorized to modestly increase (if necessary) and decrease its fees in order to manage its revenue if unforeseen circumstances negatively impact the Board's budget. Additionally, MBC would like to have authority to lower its fees when it has a sufficient reserve amount; and because authorizing a possible future fee increase of no more than 10 percent (which is substantially smaller than the currently requested fee increase) could mitigate the concerns that may arise when applicants and licensees are subject to large fee increases.

<u>Staff Recommendation:</u> MBC clearly needs additional revenue to support its activities. MBC should provide an update on the status of discussions with licensees and the Department of Finance to assist the Legislature in charting a course forward that allows MBC to have resources to conduct its important work.

MBC LICENSING ISSUES

<u>ISSUE #10:</u> (LICENSING TIMEFRAMES.) MBC is processing more applications and processing times are growing. What is the impact of licensing delays on the profession and the public, and what steps is MBC taking to achieve efficiencies?

<u>Background:</u> MBC's average processing time to review license applications has historically been approximately 30 calendar days. MBC reports that the sudden increase in application volume (including the new postgraduate training license), coinciding with the onset of the COVID-19 pandemic briefly increased the average processing time to approximately 60 calendar days. During the month of February 2021, the average number of days to review a physician and surgeon application was 29 days.

MBC is required to notify applicants within 60 working days of receipt of a physician and surgeon license application whether the application is complete and accepted for licensure or deficient. MBC experienced an approximate 26 percent increase in the number of initial license applications received between FY 2016/2017 and FY 2019/2020. MBC notes that, for comparison, in Quarter 4 of FY 2018/2019, it received approximately 1,640 physician license applications but in Quarter 4 of FY 2019/2020, the Board received approximately 2,861 license applications, a 74 percent increase in the number of license applications received during the same quarter in the previous year.

MBC advises that it has implemented several measures to address the increased workload, including approving staff overtime, reallocating staff, identifying process efficiencies, and adjusting procedures to accommodate a telework-centered office structure while working toward a paperless licensure process.

MBC is evaluating its licensure requirements and the utilization of IT solutions to address the obstacles created by hard copy documents, especially when most organizations must rely on teleworking and less office-based services during the COVID-19 pandemic. In November 2020, MBC staff identified various cost reduction/process improvement ideas in their respective units, including actions like allowing teleworking staff to take licensure application files home and return upon process completion, thereby eliminating the time and expense to scan, print, and copy files and documents and updating license processes. Specifically, BPC Section 163.5 requires licensees who have not completed their renewal to be mailed a paper renewal notice and BPC Section 2424 requires, approximately 30 days following a licensee's expiration date, if the licenses has not been renewed, MBC to mail a paper Delinquent Renewal Notice via Certified Mail. These may be unnecessary requirements as MBC reports that the vast majority (about 82 percent) of physician licensees renew online. Licensees who renew via paper face additional delays as staff await for documentation and checks to be delivered, which then must be keyed in by hand manually. Eliminating or modifying the indicated requirements that paper mailings be sent at specified times would help MBC achieve certain strategic goals.

In January 2020, the licensing program deployed one efficiency, the Direct Online Certification Submission (DOCS) portal. DOCS allows medical school and residency program staff registered with MBC to submit the required documentation electronically, which significantly reduces the overall processing time and limits the potential misdirection and loss of mail. MBC significantly expanded the utilization of DOCS across medical schools and training programs during the pandemic by increasing outreach to applicants, medical schools and postgraduate training programs. In May 2020, DOCS supported seven medical schools, 330 postgraduate training programs, and 118 registered users. By August 2020, DOCS supported 61 medical schools, 877 postgraduate training programs, and 349 users. Total medical schools and training programs utilizing DOCS increased by 56 percent from May 2020 to August 2020. As of March 15, 2020, there are 1,270 training programs,116 medical schools, and 654 users registered in DOCS.

MBC advises that it continues to explore new outreach methods and develop new professional relationships with entities that can reach a large number of training programs and residents to provide information on the application process and how to most efficiently submit required application documents to the Board. Medical school students generally graduate in May or June of each year; the postgraduate training year runs from July 1 of one year to June 30 of the following year. As part of a teaching hospital's new resident orientation held in mid-June to early-July, MBC's outreach manager is typically one of several guest speakers. Staff offers an introduction to MBC and its mission and roles, outlines the licensing process, and offers information about licensing deadlines, requirements, the consequences of inappropriate personal behaviors, training/performance issues, professionalism, and ethics. MBC staff meet one-on-one with residents to walk through their license application and answer any questions.

These new medical school graduates (generally called "first year postgraduate residents" or "PGY1s") assume that once they have graduated from medical school, they officially are a fully-functioning physician. They are unaware of the other statutory requirements they must meet before a license can be granted. Effective January 1, 2020, all applicants, regardless of the medical school attended are required to successfully complete 36 months of Board-approved postgraduate training. An applicant will need to complete 24 consecutive months of training in the same program in order to be eligible for a physician license in California. Further, a postgraduate training license (PTL) is required for all residents participating in an approved training program in California in order to practice medicine as part of their training program. The PTL must be obtained within 180 days after enrollment into the approved California program. PGY-1s may be unaware of the deadlines to obtain a PTL and the

ramifications of failing to meet those deadlines — they must cease all clinical training and may be subject to termination of employment. Either option is an extreme hardship to the teaching hospitals, which would suddenly be faced with a vacancy in the training program and in the provision of health care services.

MBC notes that while staff can no longer participate in the new resident orientations due to travel restrictions stemming from the COVID-19 pandemic, MBC's website includes detailed information about licensure requirements, deadlines, and FAQs for applicants. MBC also regularly communicates application requirements and deadline reminders to medical schools and training programs through email and the Board's list serve, and is developing new outreach materials to be delivered remotely due to COVID-19 travel restrictions.

While MBC notes it has not conducted a formal assessment on the impact of licensing delays, communications with applicants, postgraduate training program directors, hospitals, and professional associations advise that delays to issuing licenses can lead to other staff working overtime to fill unexpected vacancies, difficulty in recruiting and obtaining new hires, and can impede a facility's ability to provide health care.

<u>Staff Recommendation:</u> *MBC* should provide an update on licensing and provide the Committees with suggestions to increase efficiencies and ensure physicians and surgeons are licensed expeditiously, including necessary amendments to the Act.

ISSUE #11: (POSTGRADUATE TRAINING LICENSE.) MBC now requires physicians to complete three years postgraduate training in order to be licensed, but issues a postgraduate training license with full practice authority within the resident's training program and affiliated institutions, or as otherwise permitted in writing by the program director. What is the status of MBC's implementation of a postgraduate training license?

Background: Beginning January 1, 2020, all physician license applicants, regardless of whether they graduated school in the U.S./Canada or a foreign country, are required to satisfactorily complete a minimum of 36 months of Accreditation Council for Graduate Medical Education (ACGME) or Royal College of Physicians and Surgeons of Canada (RCPSC) accredited postgraduate training. Three years comes from the industry-recognized standard of three years of training required for board certification by American Board of Medical Specialty boards in specialties like family medicine, internal medicine, pediatrics and others. This new specification, stemming from MBC's prior sunset review, allows MBC's evaluation process to rely on programs setting the same criteria, requirements and standards and ensures that all participants in these programs meet the same criteria, requirements, and standards. Previously, MBC authorized licensure after only one year of postgraduate training and did not require completion of a full residency program, and MBC had to approve foreign medical schools rather than being able to rely on approval from another organization. The goal was to create a more effective assessment of an applicant's eligibility for licensure based on criteria other than where they attended medical school and completed undergraduate clinical rotations.

Now, all medical school graduates who match into an accredited postgraduate training program in California are required to obtain a postgraduate training license (PTL) in order to practice medicine as part of their training program. If the medical school graduate fails to obtain the PTL within 180 days after enrollment in a MBC-approved training program, or the Board denies the PTL application, all

privileges and exemptions will automatically cease. The PTL is valid for up to 39 months and may not be renewed, however, MBC may grant an extension under certain conditions.

The PTL has posed challenges for MBC and physicians alike. The Board experienced the highest number of PTL applications received in February, March, and April 2020, ranging from 836 to 970 per month. Residents who were enrolled in an ACGME-accredited training program in California on January 1, 2020, needed to obtain a PTL by June 30, 2020, and new residents had to obtain a PTL within 180 days of commencement of their training program, before Executive Order N-39-20 allowed the Director of DCA to extend the deadline to March 31, 2021. Due to this significant increase in the PTL applications received, which coincided with the onset of the COVID-19 pandemic, MBC for a period of time was reviewing new initial PTL and physician license applications approximately 60 calendar days from receipt. That time frame has since improved and during the month of February 2021, the average number of days to review a physician and surgeon application was 29 days.

MBC reports that the high volume of hard copy documents received presented challenges when trying to implement telework schedules due to COVID-19. MBC was forced to quickly evaluate and change some of its procedures to allow more tasks to be completed remotely while continuing to process a higher volume of paper applications. To ensure PTL applicants who were required to obtain a PTL by December 31, 2020 were issued licenses timely, MBC tracked and prioritized these applications, communicated deficiencies regularly to applicants, and worked closely with program directors to ensure applicants were submitting documents timely to MBC to allow for processing and to prevent any unnecessary delays.

While MBC has not conducted a formal assessment on the impact of licensing delays, but understands from communications with applicants, postgraduate training program directors, hospitals, and professional associations that delays to issuing licenses can lead to other staff working overtime to fill unexpected vacancies, difficulty in recruiting and obtaining new hires, and impede a hospital's ability to provide health care.

The PTL is intended to be an unrestricted licenses and for purposes of the Act, specifies that a resident possessing this category of recognition from MBC may engage in the practice of medicine in connection with their duties as an intern or resident physician in a MBC-approved program, including its affiliated sites, or under those conditions as are approved in writing and maintained in the postgraduate training licensee's file by the director of their program. These physicians are authorized to diagnose and treat patients; prescribe medications without a cosigner, including prescriptions for controlled substances, if individual has the appropriate Drug Enforcement Agency registration or permit and is registered with CURES; sign birth certificates without a cosigner; and sign death certificates without a cosigner. While the Act is clear on PTL authority, some agencies have policies or statutes that only authorize an unrestricted medical license holder to engage in certain activities, thus have said that residents holding a PTL are not fully authorized the same as physician licensees who have completed their three-year residency.

Concerns have been raised that:

 A PTL may not be deemed equivalent to an unrestricted medical license for purposes of Medi-Cal billing. MBC worked with DHCS and primary clinic stakeholders about whether the PTL would impact billing for the Medi-Cal Payment Prospective System (PPS) in Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs). DHCS told MBC that there were not hindrances but later issued guidance that a PTL is not an unrestricted license, and an unrestricted license is, required for an individual to enroll as a Medi-Cal Fee-For-Service (FFS) or Managed Care provider in order to work outside of a residency program, known as moonlighting. It appears that residents with a PTL who moonlight may not be able to bill Medi-Cal. Stakeholders have advised that prior to the transition to the PTL, residents could enroll as a Medi-Cal FFS or Managed Care provider and bill health plans for moonlighting services and are concerned that private health plans are following a similar direction by prohibiting payment for moonlighting services provided by residents with a PTL. This has led several health delivery systems, including FQHCs, Tribal & Rural Indian Health Centers, and private practices, are not allowing residents to moonlight. Primary care clinic representatives and family physician advocates are concerned that the inability to bill for moonlighting services decreases the number of providers available to serve patients and heavily impacts rural regions with primary care provider shortages, a demand which has only grown in light of the COVID-19 pandemic. Moonlighting also allows residents to work outside of their residency training and earn additional income to pay off their educational loans so decreased opportunities to moonlight affect patients, residents, and healthcare delivery systems. Stakeholders argue that medical school graduates applying for residency programs are less incentivized to apply in California because they are not able to bill for services conducted while moonlighting and are concerned that, with fewer applicants, the state will have a smaller pool of medical graduates to choose and recruit which will negatively impact heath centers, communities, and patients reliant on resident care and worsen the provider shortage.

MBC states in its online FAQ that "The holder of a postgraduate training license may engage in the practice of medicine only in connection with his or her duties as a resident in an ACGME-accredited postgraduate training program in California, including its affiliated sites, or under those conditions as approved in writing and maintained in the file by the director of his or her program. Accordingly, a holder of a postgraduate training license may moonlight with written authorization from the program director." The ability to moonlight does not equate to the ability to bill health plans for the reasons cited above and is further complicated by the CMS guidelines for residents. In terms of moonlighting, the resident is required to be "Fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State where the services are performed". DHCS concluded that the inability to bill health plans for moonlighting services rendered by residents with a PTL cannot be fixed administratively and requires policy revisions.

• Residents with a PTL are not able to obtain Substance Abuse and Mental Health Services Administration (SAMHSA) DEA X-waivers in order to prescribe buprenorphine and practice medication-assisted treatment. Under the Drug Addiction Treatment Act of 2000 (DATA 2000), physicians complete a mandatory eight-hour training course and obtain a DEA-X waiver to administer and/or prescribe buprenorphine medication-assisted therapy to treat opioid use disorder. DEA-X waiver protocol requires physicians to first notify the SAMHSA Center for Substance Abuse Treatment (CSAT) of their intent. To verify waiver eligibility, physicians provide their DEA number, state medical license number, and training certificate details.

Stakeholders cite several recent cases of denied DEA X-waiver applications to say that SAMSHA does not recognize the PTL as a license, despite MBC confirming, as stated in FAQs, "that a resident can apply and be issued a controlled substance permit once he or she has obtained a postgraduate training license." PTL holders with DEA prescribing authority should be able to receive a DEA X-waiver to administer and or prescribe necessary treatment for opioid use issues.

• Residents with a PTL may not be able to sign birth certificates, death certificates, and disability forms. While the Act states these are authorized activities, other agencies may require statutory or policy updates to ensure a PTL holder is able to do what they are trained and intended to do. Stakeholders note that residency programs have cited cases where residents with a PTL are not accepted as authorized signatories for essential documents. The DPH Vital Records Registration Branch mentioned in response to a death certificate signed by a resident with a PTL that "Per H&SC 102795, the medical and health section data and the time of death shall be completed and attested to by the physician and surgeon last in attendance. The board's definition of PTL is neither a licensed physician or surgeon." In January 2021, MBC was notified that DPH currently registers birth certificates attended by PTL holders and also updated its registration procedures to allow PTL holders to certify death certificates. Stakeholders say that for similar reasons, the California Employment Development Department prohibits medical graduates from signing disability forms.

Concerns have also been raised about provisions that limit a PTL holder's practice to the facility where they are training which some argue has empowered residency directors to deny residents the ability to gain practice experience by moonlighting at other facilities.

Staff Recommendation: MBC should advise the Committees on recent discussions with other agencies that impact the ability of PTL holders to fully practice. The Committees may wish to make changes to the Act in order to create efficiencies in the PTL licensing process. MBC should provide an update on discussions with stakeholders about continued barriers to practicing, allegations of program directors rejecting PTL holders' requests to practice at different facilities, and what steps need to be taken to ensure California patients receive access to quality care provided by residency program participants holding a PTL.

ISSUE #12: (MEXICO PILOT PROGRAM.) Legislation passed in 2002 established a pilot program aimed at addressing primary care and dental practitioner shortages by authorizing MBC and the Dental Board of California to issue licenses for three years to physicians and dentists from Mexico who meet specified criteria. The program has not been fully implemented. What are the barriers to MBC implementing this program? What steps has MBC taken since 2003 to put the program in place?

Background: The Licensed Physicians and Dentists Program (Mexico Pilot Program), established by AB 1045 (Firebaugh, Chapter 1157, Statutes of 2002), was designed to bring physicians and dentists from Mexico with rural experience, who speak the language, understand the culture, and know how to apply this knowledge in serving the large Latino communities in rural areas who have limited or no access to primary health care services. Proponents of the measure were concerned about addressing primary care physician and dentist shortages while maintaining a high quality of care.

The bill authorized up to 30 licensed physicians specializing in family practice, internal medicine, pediatrics, and obstetrics and gynecology and up to 30 licensed dentists from Mexico to practice medicine or dentistry in California for up to three years, and required the individuals to meet certain requirements related to training and education.

AB 1045 tasked MBC with oversight review of both the implementation of the program and an evaluation of the program once it is implemented. The bill specified that any funding necessary for the implementation of the program, including the evaluation and oversight functions, was to be secured

from nonprofit philanthropic entities and further stated that implementation of the program could not move forward unless appropriate funding was secured from nonprofit philanthropic entities.

Program participants are required to undergo a six-month orientation program approved by MBC that addresses medical protocol, community clinic history and operations, medical administration, hospital operations and protocol, medical ethics, the California medical delivery system, health maintenance organizations and managed care practices and pharmacology differences.

MBC reported at a March 2017 Board meeting that "the law expressly states that implementation of this Program shall not proceed unless appropriate funding is secured from nonprofit philanthropic entities. Funding has never been secured for this Program, so it has not yet been implemented. Once funding is secured and other requirements are met, the Board will begin the process of establishing this Program. The Board had meetings last year with interested parties and provided a fiscal estimate of the funding that would be needed to implement the Program from the Board's perspective, but to the Board's knowledge, that funding has not yet been secured. In order to implement this Program without funding from nonprofit philanthropic entities, the law would need to be amended to delete this requirement and identify a new funding source."

According to MBC's website and information provided in its 2020 sunset review report submitted to the Committees this year, MBC received the necessary philanthropic funding in 2018 to initiate the program and began taking the necessary steps for implementation.

In late 2018, AB 18 (Eduardo Garcia) sought to remove a potential barrier to the Mexico Pilot Program's implementation. That measure proposed to strike the six-month timeframe for a required orientation program that physician participants must complete. In justifying the bill, the Author stated that the 101-hour, seven module orientation curriculum will be spread over a two-month period, rather than a six-month period as the law specifies because "six months is not necessary to cover the material". The Author noted that, based on discussions program supporters had with academics at University of Berkeley School of Public Affairs, UC Davis School of Medicine, Long Beach State University, and National Autonomous University of Mexico (UNAM) only two months, at the longest, was required for the 30 Mexican doctors selected for this program to effectively process the material covered in the orientation program.

According to the Author at the time, "we have been concerned that some of the Mexican doctors selected for this program may withdraw from the program should they have to wait another six months to finish the orientation program." The Author noted that "finding alternates for this program in Mexico is very challenging because of the very high standards that must be met with the O-1 visas we will be utilizing for this program." The Author stated that "the Mexican doctors will be as prepared for practicing in California if the curriculum is spaced over 2-months or 6-months but we will not run the risk of losing the participation of these Mexican physicians."

Discussions about the original bill's intent highlighted that six-month period for the orientation curriculum was was selected arbitrarily and with no consultation with anyone at a medical school, but rather with physician stakeholders in the state to try to address concerns. The resulting language for a six month program and specific focus areas during the orientation were never updated or changed as the Program was closer to implementation. At its July 27, 2018 meeting, MBC approved the proposed orientation curriculum. According to materials provided to Board members, "the course curriculum for the Pilot Program is appropriate in volume and instruction for a six (6) month orientation program pursuant to BPC section 853(c)(2)(B)(i). In addition, the content of the course curriculum meets

appropriate California law and medical standards to sufficiently orient a participating physician to practice in California...per the information provided, the distant learning program will commence from August 20, 2018 through February 20, 2019." MBC members, in discussing striking the 6-month requirement as AB 18 bill aimed to do, expressed concerns about patient safety, particularly given that participating physicians would be practicing in underserved areas. Board members also expressed concerns about a two-tiered system, given the current transition to require a minimum of three-years postgraduate residency training, and some members highlighted changes in medical education in California over the years since AB 1045 was initially passed.

As of April 2019, MBC began accepting applications for the Mexico Pilot Program. MBC received the required funding commitments necessary or program implementation in December 2020. Also, related to the funding issue, the contract for the evaluation the program that is required pursuant to BPC section 853(j) must have sufficiently progressed through the approval process of both the participating medical school and the DCA to ensure that the contract will be approved and that appropriate funding is in place as required before issuing the licenses. MBC reports that it has received and evaluated approximately 29 applications (25 applicants are committed to the program). MBC was ready to start issuing licenses in February 2021 to all of the applicants who had met the requirements and was asked by program representatives to delay the issuance while the applicants prepared their visa applications. The issue of securing visas for participants has been raised as a potential challenge, one that is clearly outside of MBC's control.

During the last several months, MBC reports that it has been working closely with each applicant in providing updates on the status of their application; working collaboratively with the Business, Consumer Services and Housing Agency, DCA, and program representatives on the advancement of the program, and communicating with the non-profit healthcare clinics to ensure all deficiencies are met.

In late February 2021, the Board began the process of advertising for the vacant Mexico Pilot Program position and working with the Department of Finance on securing the necessary appropriation to implement the program over the next three years.

<u>Staff Recommendation:</u> MBC should update the Committees on the status of The Licensed Physicians and Dentists Program, including remaining barriers to implementation and funding options. MBC should advise the Committees of statutory changes necessary to the Act in order for the program to be implemented.

ISSUE #13: (AB 2138.) What is the status of MBC's implementation of Assembly Bill 2138 (Chiu/Low) and are any statutory changes needed to enable the Board to better carry out the intent of the Fair Chance Licensing Act?

Background: In 2018, Assembly Bill 2138 (Chiu/Low, Chapter 995, Statutes of 2018) was signed into law, making substantial reforms to the license application process for individuals with criminal records. Under AB 2138, an application may only be denied on the basis of prior misconduct if the applicant was formally convicted of a substantially related crime or was subject to formal discipline by a licensing board. Further, prior conviction and discipline histories are ineligible for disqualification of applications after seven years, with the exception of serious and registerable felonies, as well as financial crimes for certain boards. Among other provisions, the bill additionally requires each board to report data on license denials, publish its criteria on determining if a prior offense is substantially related to licensure, and provide denied applicants with information about how to appeal the decision

and how to request a copy of their conviction history. These provisions are scheduled to go into effect on July 1, 2020.

Because AB 2138 significantly modifies current practice for boards in their review of applications for licensure, it was presumed that its implementation will require changes to current regulations for every board impacted by the bill. It is also likely that the Board may identify potential changes to the law that it believes may be advisable to better enable it to protect consumers from license applicants who pose a substantial risk to the public.

The Board has denied 12 licenses or registrations over the past four fiscal years based on criminal history that the Board determined was substantially related to the qualifications, functions, or duties of the profession, pursuant to BPC section 480. The denials were as follows: Nine physician licenses, two polysomnography registrations. The Board also denied one PTAL. Below is a breakdown of each instance of denial by fiscal year.

Criminal Conviction Denials				
FY 16/17	FY 17/18	FY 18/19	FY 19/20	
3	5	4	0	

<u>Staff Recommendation:</u> *MBC* should provide an update on its implementation of the Fair Chance Licensing Act, as well as relay any recommendations it has for statutory changes.

ISSUE #14: (SPECIAL FACULTY PERMITS AND ACADEMIC MEDICAL CENTERS) MBC issues Special Faculty Permits (SFP) for individuals to practice in California who are determined to be academically eminent. AB 2273 (Bloom, Chapter 280, Statutes of 2020) authorized an academic medical center (AMC) to submit applications SFPs and authorized a SFP holder, a visiting fellow, and a holder of a certificate of registration to practice medicine within the AMC and its affiliated facilities without obtaining full licensure. Are changes necessary to ensure the quality of AMCs?

Background: BPC Section 2168 authorizes MBC to issue a SFP to a person who meets specific eligibility requirements, including that they:

- are clearly outstanding in a specific field of medicine or surgery
- are offered a full-time academic appointment at the level of full professor, or
- a great need exists and the individual has been offered a full-time academic appointment at the level of associate professor.

This SFP authorizes the holder to practice medicine only within the facilities of the applicable medical school and any formally-affiliated institutions. AB 2273 added AMCs as eligible sponsors to allow an academically eminent international physician to obtain a SFP and gain authority to practice medicine in the AMC and its affiliated institutions.

MBC has Special Faculty Permit Review Committee (SFPRC) that reviews SFP applications and makes recommendations to the MBC about whether the individual should be approved. The review

committee consists of one representative from each of the eleven medical schools in California, two MBC members, and one AMC representative. MBC reports that a SFP must be renewed every two years. At the time of the SFP holder's renewal, the SFP holder must have the dean certify that the permit holder continues to meet the eligibility criteria, that the individual is still employed solely at the sponsoring institution, that the individual continues to possess a current medical license in another state or country, and that the individual is not subject to having the SFP denied. The SFP holder is required to comply with the same CME requirements as licensed physicians and surgeons. SFP holders are listed on MBC's website with licensed physicians to ensure that members of the public can verify an SFP holder's current status and public record. The complaint process is the same for an SFP holder as it is for any complaint MBC receives for a licensed physician.

According to MBC, in 2016, it surveyed nine of the ten medical schools in California asking for input as to whether the SFP is still needed. The survey results were presented at the May 2016 Licensing Committee meeting and at the September 2016 SFPRC Meeting. The SFPRC Members determined there were no statutory changes needed for the SFP.

In addition to the SFP, MBC provides other limited exemptions for individuals to practice as a physician and surgeon in California, including: an international physician or surgeon authorized to participate in a visiting fellowship at a sponsoring medical school or AMC; an international physician or surgeon who is licensed in their country can be offered a faculty position for one year, subject to renewal two times before a licensing plan is required renewed twice to teach at a medical school or AMC; and a medical student enrolled in an international medical school recognized by MBC may practice medicine in a MBC-approved clinical training program.

Given the expansion of exemptions and SFP authority to AMCs through AB 2273, concerns were raised as to whether AMCs were defined appropriately to ensure that quality given that physicians would be allowed to practice without being fully licensed. AB 2273 defined AMC as an entity that meets all the following:

- The facility conducts both internal and external peer review of the faculty for the purpose of conferral of academic appointments on an ongoing basis of clinical and basic research for the purpose of advancing patient care;
- The facility trains a minimum of 250 residents and postdoctoral fellows on an annual basis commencing each January 1; and,
- The facility has more than 100 research students and postdoctoral researchers annually and foreign medical graduates in clinical research, offers clinical observership training, and has an intern and resident-to-bed ratio meeting the federal Centers for Medicare and Medicaid Services definition as a major teaching hospital and conducts research in an amount of \$100 million dollars or more annually.

Specifically, there is no requirement that AMCs are accredited and the Act may need to be amended to add this measure of quality, including that AMCs sponsoring SFP holders are accredited by the Western Association of Schools and Colleges and ACGME.

It would be helpful for the Committees to understand the length of time individuals can practice in California through any of these pathways and to determine what changes are necessary to balance patient care with the opportunity for learning provided by eminent physicians and surgeons.

<u>Staff Recommendation:</u> MBC should advise on the status of expanding current options for international physicians to AMCs, as well as provide information on the numbers of applicants for SFPs and other exemptions since the passage of AB 2273. The Committees may wish to amend the Act to ensure that AMCs are properly accredited.

MBC ENFORCEMENT ISSUES

<u>ISSUE #15:</u> (MANDATORY REPORTING TO MBC.) MBC receives reports related to physicians from a variety of sources. These reports are critical tools that ensure MBC maintains awareness about its licensees and provide important information about licensee activity that may warrant further MBC investigation. MBC may not be receiving reports as required and enhancements to the Business and Professions Code may be necessary to ensure MBC has the information it needs to effectively do its job.

<u>Background:</u> There are a significant number of reporting requirements outlined in BPC designed to inform MBC about possible matters for investigation. MBC includes information in its Newsletter regarding mandatory reporting, conducts presentations regarding requirements for reporting and posts information on its website regarding the submission of required reports. Mandatory reports to MBC include:

<u>BPC 801.01</u> requires MBC to receive reports of settlements over \$30,000 or arbitration awards or civil judgments of any amount. The report must be filed within 30 days by either the insurer providing professional liability insurance to the licensee, the state or governmental agency that self-insures the licensee, the employer of the licensee if the award is against or paid for by the licensee or the licensee if not covered by professional liability insurance.

MBC reports that in general, these reports appear to be submitted to MBC within the 30 day timeframe. MBC states that it has reminded insurers of the reporting requirements and the importance of providing correct data. The average dollar settlements for the past three years has been: FY 17/18 - \$671,365.39; FY 18/19 - \$760,911.79; FY 19/20 - \$543,831.41.

<u>BPC 802.1</u> requires physicians to report indictments charging a felony and/or any convictions of any felony or misdemeanor, including a guilty verdict or plea of no contest.

MBC states that it appears to be receiving these incidents as required. MBC confirms that licensees are reporting these criminal charges through its receipt of arrest and conviction notifications that come to MBC from DOJ. Failure to report a criminal conviction to MBC results in a citation.

<u>BPC Section 802.5</u> requires a coroner who receives information, based on findings reached by a pathologist that indicates that a death may be the result of a physician's gross negligence, to submit a report to MBC. The coroner must provide relevant information, including the name of the decedent and attending physician as well as the final report and autopsy.

As was the case during the prior review, MBC reports that it is not receiving these reports as required, citing the submission of only 1 report in FY 2019/20. Gross negligence may be a hard

cause of death for a coroner to determine, which may lead to the low number of reports MBC receives. However, increased reporting by coroners to MBC when cause of death may be related to a physician could enhance MBC's enforcement efforts. The issue of coroners' reports is particularly salient for deaths related to prescription drug overdose. In those instances where a coroner determines cause of death is drug toxicity, and where the coroner findings deal with a young person, who is not a cancer patient on hospice or someone in a health facility setting, who was found dead in possession of various opioid combinations, the prescribing doctor and his or her practices may need to be looked into. MBC should receive coroner's reports as required by law and may benefit from receiving coroners reports where cause of death is expanded, beyond just gross negligence.

<u>BPC Sections 803, 803.5 and 803.6</u> require the clerk of a court that renders a judgment that a licensee has committed a crime, or is liable for any death or personal injury resulting in a judgment of any amount caused by the licensee's negligence, error or omission in practice, or his or her rendering of unauthorized professional services, to report that judgment to MBC within 10 days after the judgment is entered. In addition, the court clerk is responsible for reporting criminal convictions to MBC and transmitting any felony preliminary hearing transcripts concerning a licensee to MBC.

<u>BPC Section 805</u> is one of the most important reporting requirements that allows MBC to learn key information about a physician or surgeon. Section 805 requires the chief of staff and chief executive officer, medical director, or administrator of a licensed health care facility to file a report when a physician's application for staff privileges or membership is denied, or the physician's staff privileges or employment is terminated or revoked for a medical disciplinary cause. The reporting entities are also required to file a report when restrictions are imposed or voluntarily accepted on the physician's staff privileges for a cumulative total of 30 days or more for any 12-month period. The report must be filed within 15 days after the effective date of the action taken by a health facility peer review body.

MBC compares the reports it receives to information contained in the National Practitioners Databank and has determined it is likely receiving reports when a facility believes a report should be issued. MBC has attempted to enhance knowledge of this requirement.

<u>BPC Section 805.01</u> is a similarly extremely important requirement. The law requires the chief of staff and chief executive officer, medical director, or administrator of a licensed health care facility to file a report within 15 days after the peer review body makes a final decision or recommendation to take disciplinary action which must be reported pursuant to section 805. This reporting requirement became effective January 2011 and is only required if the recommended action is taken for the following reasons:

- Incompetence, or gross or repeated deviation from the standard of care involving death or serious bodily injury to one or more patients in such a manner as to be dangerous or injurious to any person or the public.
- The use of, or prescribing for or administering to him/herself, any controlled substance; or the use of any dangerous drug, as defined in BPC Section 4022, or of alcoholic beverages, to the extend or in such a manner as to be dangerous or injurious to the licentiate, or any other persons, or the public, or to the extent that such use impairs the ability of the licentiate to practice safely.

- Repeated acts of clearly excessive prescribing, furnishing or administering of controlled substances or repeated acts of prescribing, dispensing, or furnishing of controlled substances without a good faith effort prior examination of the patient and medical reason therefor.
- Sexual misconduct with one or more patients during a course of treatment or an examination.

The purpose of 805.01 reports is to provide MBC with early information about these serious charges so that MBC may investigate and take appropriate action to further consumer protection at the earliest possible moment. Accordingly, for any allegations listed above, the Legislature determined that an 805.01 report must be filed once a formal investigation has been completed, and a final decision or recommendation regarding the disciplinary action to be taken against a physician has been determined by the peer review body, even when the physician has not yet been afforded a hearing to contest the findings.

MBC has attempted to enhance knowledge of this requirement but is not receiving reports as required. According to MBC, it writes an article every January in its Newsletter, "Mandatory Reporting Requirements for Physicians and Others," that reminds entities they required to file 805.01 reports. MBC reports that it also wrote a separate article for the Fall 2015 Newsletter, "Patient Protection is Paramount: File Your 805.01 Reports," in an effort to boost compliance with the requirement.

Given the seriousness of the nature of these reports, SB 798 enhanced the penalties for an entity's failure to file an 805.01 report to allow MBC to fine an entity up to \$50,000 per violation for failing to submit an 805.01 report, or \$100,000 per violation if it is determined that the failure to report was willful.

BPC Section 805.8 became law upon the passage of SB 425 (Hill, Chapter 849, Statutes of 2020). A health care facility or other entity that makes any arrangement under which a healing arts licensee is allowed to practice or provide care for patients must file a report of any allegation of sexual abuse or sexual misconduct made against a healing arts licensee by a patient, if the patient or the patient's representative makes the allegation in writing, to the agency within 15 days of receiving the written allegation of sexual abuse or sexual misconduct. MBC anticipated new enforcement cases stemming from this requirement and it would be helpful for the Committees to understand what outreach MBC has done to ensure it is made aware of serious allegations this reporting requirement covers.

BPC Section 2216.3 requires accredited outpatient surgery settings to report an adverse event to MBC no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected.

In FY 2014/2015 the Board received 104 adverse event reports. In FY 2015/2016 the Board received 111 adverse event reports. In FY 17/18, 18/19, and 19/20, the Board received 173, 303, and 218 adverse event reports, respectively. Adverse events appear to be reported as required, with the number of reports received by MBC increasing, as outpatient surgery settings

became familiar with the law and gained an understanding of the types of events that should be reported. Enhancements to this requirement are discussed in Issue # 19 below.

BPC Section 2240(a) requires a physician and surgeon who performs a medical procedure outside of a general acute care hospital that results in the death of any patient on whom that medical treatment was performed by the physician and surgeon, or by a person acting under the physician and surgeon's orders or supervision, to report, in writing, on a form prescribed by the MBC, that occurrence to MBC within 15 days after the occurrence.

For FY 17/18, 18/19, 19/20 respectively, the Board has received 16, 15, and 7 reports where a physician or surgeon performing a medical procedure outside of a general acute care hospital that resulted in death. MBC has worked with the Legislature to ensure that deaths from all procedures, rather just scheduled procedures, are reported.

<u>Staff Recommendation:</u> MBC should provide an update to the Committees on the status of receiving mandatory reports. The Committees may wish to enhance reporting requirements where necessary to ensure MBC is made aware of important information and actions that impact patient care which MBC may need to act upon.

ISSUE #16: (COMPLAINTS.) Complaints are the heart of MBC's enforcement program. Delays in complaint processing can have grave effects on patients and the public and compound MBC's efforts to protect consumers. In consumer satisfaction surveys, MBC consistently receives unfavorable feedback and response for its handling of complaints. What efforts is MBC taking to process complaints, particularly with a rise in the number of complaints received?

Background: Accepting, processing and acting on complaints from patients, the public, MBC staff, other agencies and other sources is a primary mechanism by which MBC can ensure that licensees are in compliance with the Act and that patients have options for action in the event that their physician violates the law. The timely processing of complaints provides MBC with critical information about their licensees and assists in prioritizing workloads.

The law establishes MBC's prioritization for complaints and outlines the following as the highest priority for MBC:

- Complaints related to gross negligence, incompetence or repeated negligent acts that involve death or serious bodily injury to one or more patients, such that the physician and surgeon represents a danger to the public
- Drug or alcohol abuse by a physician and surgeon involving death or serious bodily injury to a patient
- Repeated acts of clearly excessive prescribing, furnishing, or administering of controlled substances or repeated acts of prescribing, dispensing, or furnishing of controlled substances without a good faith prior examination of the patient and medical reason therefor
- Repeated acts of clearly excessive recommending of cannabis to patients for medical purposes, or repeated acts of recommending cannabis to patients for medical purposes without a good faith prior examination of the patient and a medical reason for the recommendation

- Sexual misconduct with one or more patients during a course of treatment or an examination
- Practicing medicine while under the influence of drugs or alcohol
- Repeated acts of clearly excessive prescribing, furnishing, or administering psychotropic medications to a minor without a good faith examination of the patient and medical reason therefor.

Complaints are brought to MBC's attention through a variety of sources, including patients, family members, licensees, other state agencies, media, mandated reporters, other state's disciplinary actions, and any other means of receiving information about a physician who may be violating the law. While the steps to process a complaint may be different based upon the type of complaint, all complaints go through the same process of triage and initial review by the MBC's Central Complaint Unit (CCU), then to investigation, then, if warranted by either MBC's non-sworn investigators or the DCA's sworn investigators, prosecution by the OAG.

Complaints are confidential until substantiated and the complaint and investigation result in some type of formal, public action. This is not the case for all DCA boards, notably the Contractors State License Board which is required (BPC Section 7124.6) to "make available to members of the public the date, nature, and status of all complaints on file against a licensee that do either of the following: (1) Have been referred for accusation. (2) Have been referred for investigation after a determination by board enforcement staff that a probable violation has occurred, and have been reviewed by a supervisor, and regard allegations that if proven would present a risk of harm to the public and would be appropriate for suspension or revocation of the contractor's license or criminal prosecution." It would be helpful for the Committees to understand the impact of making complaint information available and to better understand the historical circumstances that led to MBC complaints remaining confidential.

The Act requires MBC to set as a goal that on average, no more than 180 days will elapse from the receipt of a complaint to the completion of an investigation. The law also states that if MBC believes that the case involves complex medical or fraud issues or complex business or financial arrangements, this goal should be no more than one year to investigate. According to MBC, due to an increase in the number of complaints received, staff vacancies affecting both desk and field investigation workloads, and complexity of the cases, the overall average days to investigate a complaint was 202 days in FY 2019/2020. This is higher than the figure of 170 days in FY 2018/which MBC attributes to all-time highs in receiving new complaints.

MBC must acknowledge complaints within 10 days of receipt. In early 2020, the MBC changed processes to ensure the processing of new complaints in 10 days or less and reports that it is meeting or exceeding the mandated timeframe.

MBC states that individuals who file a complaint are notified at various stages within the enforcement process. Upon receipt and opening of a complaint, an acknowledgement letter is sent to the complainant. This letter informs the complainant that MBC received their complaint and that if they have additional information they may submit it to CCU for review. MBC also sends a letter to patients or plaintiffs in malpractice cases who may be unaware that MBC received a mandated report complaint. This letter informs them that MBC received this report, asks them to provide additional information they may have, and outlines MBC's statute of limitations.

When MBC sends a request to the complainant for their release of medical records, MBC also informs the complainant that they can provide additional information regarding their complaint. MBC states that during the complaint review process, if the complainant calls MBC, staff also informs them that they may provide additional information.

For quality of care cases, the complainant is notified that all the medical records have been received and that the complaint is going to be sent to a medical consult expert for review. For all cases, if it is determined that the complaint is moving to formal investigation, the complainant is sent a letter notifying them of this transition of the case. Once the complaint goes to formal investigation, MBC states the complainant will be contacted by the investigator. If the matter is referred to OAG, the complainant receives a letter notifying them the matter has been referred and also receives a letter and a copy of the accusation, if one is filed. If disciplinary action is taken, the complainant also receives a copy of the final decision in the matter. MBC says that complainants are informed that the complaint they filed with MBC has led to disciplinary action.

MBC says it has made a number of enhancements and revisions to the complaint forms, online forms, and public information to provide more accessibility, efficiency and explanation of the process to the public. Complaint forms were revised to allow for more specific information from the complainant and the form now includes a release for the patient's records to allow for a quicker processing time of the complaint. The online forms were set up to mirror the paper forms and allow for the release(s) to be sent at the time of submission of the complaint. In 2019, MBC created a new brochure outlining the complaint process that is available to the public in print or on its website. MBC notes that it is currently working on IT options in order to move to a fully paperless complaint system.

MBC reports that the number of complaints received continues to increase. The average number of complaints received in FY 2013/14 to FY 2015/16 was 8,425. In the past three year cycle, FY 2017/18 to FY 2019/20, the average was 10,695 complaints, or an increase of approximately 27 percent over the prior reported average. Staffing has not increased significantly to reflect this increased workload change. CCU and CIO have placed a significant focus on addressing pending cases and those cases that are over one year in age. During the initial stages of the COVID-19 pandemic response, MBC encountered a reduction in the number of incoming complaints and allowed staff to catch up on pending and aging matters.

In early 2020, there were over 500 cases awaiting expert review. As of July 2020, MBC reports that the backlog has been eliminated and cases are being followed up on by CCU staff within 30 days of assignment to a medical reviewer.

It would be helpful for the Committees to understand whether MBC treats complaints received by patients any differently than complaints generated by MBC staff in response to a report or news media article. It would be helpful for the Committees to better understand how MBC follows up on complaints, particularly how MBC contacts individuals who file complaints about their physicians to either gain additional information or to alert the individual of the status of a case, beyond the letters sent to complainants.

<u>Staff Recommendation:</u> MBC should update the Committees on its complaints process, giving particular attention to the work MBC does to ensure that patients have an opportunity to provide information that may be critical in determining what next steps to take and what efforts MBC needs

to take to ensure individuals who file complaints are proactively informed throughout the process. MBC should provide information on the historical rationale for treating complaints as confidential until formal action is taken, rather than investigation.

ISSUE #17: (ENFORCEMENT OPTIONS.) MBC has looked for enforcement cost savings and believes it should be authorized to have additional methods of resolving enforcement actions in what MBC calls a "non-adversarial manner". Should the Act be updated to allow MBC to have other options outside of traditional enforcement? What types of cases would benefit from these efforts? What patient and public protection impacts would these efforts have?

<u>Background:</u> According to MBC, a steady increase in enforcement costs and a relatively stagnant income stream has resulted in a worsening fiscal position that threatens MBC financial independence and sustainability. MBC states that increasing timelines to complete enforcement actions require a fresh look at the regulatory toolkit available and is trying to determine what additional regulatory approaches MBC should have in order to enhance the effectiveness of enforcement actions and "align the Board with best international practice."

MBC states that it has a limited number of regulatory tools at its disposal to directly resolve enforcements matters at an early stage without requiring a formal regulatory process. MBC does have the ability to issue public letters of reprimand prior to or following a formal accusation and issues these letters in circumstances where multiple simple departures or a single, extreme departure from the standard of care is established. Letters are published on MBC's website and may include certain educational requirements for remediation. A public letter of reprimand issued pursuant to BPC Section 2233 for minor violations is available to the public indefinitely but posted on MBC's website for 10 years from the effective date of the decision. A public letter of reprimand issued pursuant to BPC section 2221.05 is a non-disciplinary administrative action issued at the time of licensure, and purged three years from the date of issuance. These letters are come directly from MBC and do not require any further legal or enforcement process steps. MBC states that it uses these letters to educate an applicant who has committed minor violations that MBC does not believe merit the denial of a license or require probationary status, as well as to alert the public about the issue. MBC is also authorized to issue "warning" or "educational" letters to licensees that identify a potential shortcoming in the licensee's practice which not rise to the level of multiple simple departures or a single extreme departure from the standard of care, along with a recommended remedial action. MBC does not publish these letters and they are not legally binding. MBC states that these have been issued in the past but the practice of issuing the letters by the Board has fallen into disuse in recent times.

MBC is proposing increase the use of both types of letters, noting that letters of reprimand may often achieve the same ultimate objective currently achieved in enforcement actions only after cases go through the complete enforcement process, but at considerably less time and cost. In addition, the use of warning and educational letters may be a useful instrument in raising standards of practice in cases for which no other regulatory instruments are available.

MBC believes it should have additional method of resolving enforcement actions in what MBC calls a "non-adversarial manner", specifically a letter of advice (sometimes referred to as "stipulation to informal disposition"). MBC believes this option should be available in matters where the threshold for a public letter of reprimand has not been met. For example, MBC cites circumstances where there is only a single simple departure from the standard of care or a view is taken that there may not be clear and convincing evidence available to support a case against the licensee. According to MBC, the letter would be a letter of advice, not reprimand or warning, and may include simple conditions, such as the

taking of an educational course or other straightforward method of remediation. MBC envisions this letter of advice as a confidential communication issued when there is no concern about the licensee's fitness to practice and where the proposed action contained in a letter is deemed sufficient to protect the public. MBC states that these letters have proven to be useful at resolving matters efficiently and effectively in other jurisdictions, including 20 state medical boards that have and would result in reduced investigative timelines.

It would be helpful for the Committees to understand what types of issues, circumstances and situations may benefit from an advice letter. It would be helpful for the Committees to know what criteria this tool will be evaluated on to ensure it is, as MBC states, sufficient to protect the public.

<u>Staff Recommendation:</u> *MBC* should update the Committees on the impacts of these additional enforcement options. The Committees may wish to authorize MBC to have new enforcement authorities as described above while ensuring that patient protection is prioritized.

<u>ISSUE #18:</u> (SETTLEMENTS.) Like many licensing boards, MBC enters into settlement agreements with most plaintiffs in enforcement cases. What is the practical impact of settlements on patients, the public, licensees, and significantly, MBC's resources?

Background: Licensing boards often resolve a disciplinary matter through negotiated settlement, typically referred to as a "stipulated settlement." This may be done, rather than going to the expense of lengthy administrative hearing on a disciplinary matter. According to information from the Citizen Advocacy Center (a national organization focusing on licensing regulatory issues nationwide) "It is not uncommon for licensing boards to negotiate consent orders [stipulated settlements] 80% of the time or more." Similar to a plea bargain in criminal court, a licensee admits to have violated charges set forth in the accusation and accepts penalties for those violations. A stipulated settlement is not necessarily good or bad from a public protection standpoint. However, it is important for a licensing board to look critically at its practices to make sure that it is acting in the public's interest when it enters into a stipulated settlement and that it is acting in the best way to protect the public in each of these stipulated decisions.

Boards rely on disciplinary guidelines adopted through the regulatory process to guide disciplinary actions. Disciplinary guidelines are established with the expectation that ALJs hearing a disciplinary case, or proposed settlements submitted to a program for adoption, will conform to the guidelines. If there are mitigating factors, such as a clear admission of responsibility by the licensee early on in the process, or clear willingness to conform to board-ordered discipline, or other legal factors, a decision or settlement might vary from the guidelines. At other times in a disciplinary case there can be problems with the evidence, but the licensee admits to wrongdoing in a matter and may be willing to settle a case without going to a formal hearing.

MBC uses its Disciplinary Guidelines (16 CCR section 1361) and the Uniform Standards for Substance-Abusing Licensees (Uniform Standards) (16 CCR section 1361.5) as the framework for determining the appropriate penalty for charges filed against a physician. BPC Section 2229 identifies that protection of the public shall be the highest priority for MBC, but also requires that wherever possible, the actions should be calculated to aid in the rehabilitation of the licensee.

While the Disciplinary Guidelines and Uniform Standards frame the recommended penalty, MBC states that the facts of each individual case may support a deviation from the guidelines. After an

accusation and/or petition to revoke probation is filed, a respondent physician must file a Notice of Defense within 15 days indicating they intend to present a defense to the accusation and/or petition to revoke probation or that they are interested in a settlement agreement. If the individual requests a hearing, existing law (Government Code Sections 11511.5 and 11511.7) requires that a prehearing conference be held to explore settlement possibilities and prepare stipulations, as well as schedule a mandatory settlement conference, in an attempt to resolve the case through a stipulated settlement before proceeding to the administrative hearing level.

The DAG assigned to a case reviews it, along with any mitigation provided, the strengths and weaknesses of the case, MBC's Disciplinary Guidelines, and, when applicable, any prior disciplinary action against the respondent physician to assist in drafting a settlement recommendation that frames the recommended penalty. MBC states that this settlement recommendation takes into account consumer protection but also BPC Section 2229(b) requirements for MBC to "take action that is calculated to aid in the rehabilitation of the licensee, or where, due to a lack of CE or other reasons, restriction on scope of practice is indicated, to order restrictions as are indicated by the evidence." The DAG's recommendation is then reviewed and either approved or edited by the supervising DAG. Once that approval is received, the DAG submits the settlement recommendation to MBC's executive director for review and consideration.

MBC's executive director (and/or deputy director and/or chief of enforcement) reviews the settlement recommendation using the same criteria as the DAG and either approves or changes the settlement recommendation. The DAG then negotiates with the respondent physician and/or their counsel to settle the case with the recommended penalty. Both the prehearing settlement conference and the mandatory settlement conference are assisted by an ALJ who reviews the case and hears information from the DAG and the respondent physician and/or their counsel while helping to negotiate the settlement. During the settlement conference, the appropriate MBC representative must be available to authorize any change to the previously agreed-upon settlement recommendation.

If a settlement agreement is reached, the stipulated settlement document must be approved by a MBC panel, unless the settlement is for a stipulated license surrender. MBC then has the ability to adopt the settlement as written, request changes to the settlement, or request the matter go to hearing. In the process of settling a case, public protection is the first priority, and must be considered with rehabilitation of the physician. When making a decision on a stipulation, the panel members are provided the strengths and weaknesses of the case, and MBC states that they weigh all factors.

MBC states that settling cases by stipulations that are agreed to by both sides facilitates consumer protection by notifying the public and rehabilitating the physician in a more expeditious manner. By entering into a stipulation, it puts the individual on probation or restriction sooner and the public is able to see the action taken by MBC in a more timely manner than if the matter went to hearing. In addition, MBC says it may get more terms and conditions through the settlement process than would have been achieved if the matter went to hearing.

The information below highlights the number of cases, post-accusation, that MBC settled for the past four years, and corresponding percentages as compared to all cases referred for formal discipline.

Fiscal Year	16/17	17/18	18/19	19/20
Post-Accusation/Petition to Revoke				
Probation/Statement of Issues Cases	322	284	290	281
resulting in a Settlement				
Post-Accusation/Petition to Revoke				
Probation/Statement of Issues Cases	87	47	76	44
resulting in a Hearing				
*Post-Accusation/Petition to Revoke				
Probation/Statement of Issues Cases	35	38	40	22
resulting in a Default Decision				

Fiscal Year	16/17	17/18	18/19	19/20
Percentage of Cases resulting in a Settlement	75%	82%	77%	84%
Percentage of Cases resulting in a Hearing	18%	10%	15%	11%
*Percentage of Cases resulting in a Default Decision	7%	8%	8%	5%

^{*}Default decisions are included as they represent another method through which a disciplinary action can be taken and should be considered in the types of case resolutions

MBC says that the settlement process is the most expeditious way to resolve cases in a manner that provides an adequate level of consumer protection and avoids the additional costs and risks associated with taking a case to an administrative hearing.

Over the prior four fiscal years, MBC settled an average of 79.5 percent of its disciplinary proceedings.

The negative impact on patients stemming from settlements can be significant. For example, in 2000, one physician entered into a stipulated settlement with MBC for violations that occurred in 1996 and 1997. The physician was placed on probation for three years. The physician was restored to full license status in 2003 but again placed on probation for five years based on a settlement. MBC's most recent accusation filed against the physician cites gross negligence, repeated negligence and failure to keep adequate and accurate records related to the wrongful deaths of a patient and her unborn son last year.

Concerns have been raised for years that MBC settles with physicians and surgeons for terms, penalties, or conditions that are below MBC's own Disciplinary Guideline standards. It would be helpful for the Committees to understand why MBC would settle a disciplinary case for terms less than those stated in the Disciplinary Guidelines, including the patient protection rationale for settling administrative cases for terms that are below those outlined in Disciplinary Guidelines. It would be helpful for the Committees to understand if recommendations to settle for terms below those in the Disciplinary Guidelines come from OAG, MBC members on a panel, MBC staff, or others.

<u>Staff Recommendation:</u> MBC should provide information to the Committees about the frequency of settlements entered into below the standards, terms, and conditions suggested in the Disciplinary Guidelines, as well as provide an update on the patient impacts stemming from repeated settlement agreements with violating physicians and surgeons.

<u>ISSUE #19:</u> (ENFORCEMENT ENHANCEMENTS.) Various enhancements to the Act may be necessary for MBC to ensure public protection.

<u>Background:</u> Amendments to the Act may assist MBC in its ability to take swift disciplinary action when necessary and warranted. Enhancement include additional inspection authority, expanded record review, obtaining pharmacy records in a timely manner, and revisions to statute of limitations

Additional inspection authority. MBC is authorized to conduct inspections and review medical records in the office of a licensee, but subject to such severe limitations that MBC reports that these inspections and records review are virtually meaningless and ineffective. MBC proposes updating the Act to enable qualified and properly trained investigators with the CIO and with the HQIU, along with medical consultants when desired, to conduct inspections and review patient medical records of licensed medical professionals in their professional office. The proposal would enable CIO and HQIU investigators and medical consultants to view the records of specific patients to assist in targeting, with greater precision, the information sought in an investigative subpoena. MBC believes this review would greatly strengthen its position in subpoena enforcement actions, wherein MBC is required to establish good cause to believe that misconduct has occurred, sufficient to overcome a patient's right to privacy.

MBC believes that this enhanced inspection authority would also assist in determining whether necessary in-house processes at the office or facility where an incident occurred were capable of being performed safely when patient treatment may be the subject of an investigation. MBC says that investigators will be able to observe, for example, whether crash carts and other equipment expected to be found in an OSS or medical office are present and in good working order. MBC believes that early on-premise investigation will also help investigators to quickly determine whether further investigation is warranted. In certain cases, MBC states that a draft investigation report could be provided to an MBC medical consultant for further assessment, and could result in earlier closure of meritless complaints or cases where there is insufficient evidence to prove a case by clear and convincing evidence.

MBC's proposed legislation is similar to that in Government Code section 12528.1, enacted in 2005, which permits the Bureau of Medi-Cal Fraud and Elder Abuse (BMFEA) to conduct inspections of Medi-Cal providers for the underlying purpose of carrying out the investigation and enforcement duties of the BMFEA.

This proposal would add a new section to the BPC as follows:

Business and Professions Code Section 2220.1

- a) Any investigator with the board or the Department of Consumer Affairs, Health Quality Investigation Unit, conducting an investigation of any individual licensed by the board, shall have the authority to inspect, at any time, with or without the assistance of a medical consultant at the investigator's discretion, the business location and records, including patient and client records, of any such licensee for the purpose of carrying out the duties of the board as set forth in Section 2220.
- b) <u>The board and the department shall provide all investigators assigned to lead an inspection team for conducting inspections under subdivision (a) with basic training</u>

- on the relevant statutes and regulations governing the types of facilities to be inspected.
- c) The board and department in conjunction with the Department of Justice, Civil Division, Health Quality Enforcement Section, shall develop protocols to ensure that inspections conducted pursuant to this section are conducted during normal business hours and are completed in the least intrusive manner possible.

Records Review. Under current law, BPC section 2225(a), limits any in office review of records to those that pertain to patients who have complained to the Board. Given that limitation, in most cases investigators will simply request a copy of the records pursuant to a release signed by the patient, rather than inspecting the records in the office of the licensee.

To make the Board's inspection authority meaningful, and, in particular, to assist investigators in developing good cause to support a subpoena for the records of uncooperative patients, the Board seeks the following changes to BPC Section 2225:

- (a) Notwithstanding Section 2263 and any other law making a communication between a physician and surgeon or a doctor of podiatric medicine and his or her their patients a privileged communication, those provisions shall not apply to investigations or proceedings conducted under this chapter. Members of the board, the Senior Assistant Attorney General of the Health Quality Enforcement Section, members of the California Board of Podiatric Medicine, and deputies, employees, agents, and representatives of the board or the California Board of Podiatric Medicine and the Senior Assistant Attorney General of the Health Quality Enforcement Section shall keep in confidence during the course of investigations, the names of any patients whose records are reviewed and shall not disclose or reveal those names, except as is necessary during the course of an investigation, unless and until proceedings are instituted. The authority of the board or the California Board of Podiatric Medicine and the Health Quality Enforcement Section to examine records of patients in the office of a physician and surgeon or a doctor of podiatric medicine is limited to records of patients who have complained to the board or the California Board of Podiatric Medicine about that licensee.
- (b) Notwithstanding any other law, the Attorney General and his or hertheir investigative agents, and investigators and representatives of the board, including investigators with the Department of Consumer Affairs, Health Quality Investigation Unit, or the California Board of Podiatric Medicine, may inquire into any alleged violation of the Medical Practice Act or any other federal or state law, regulation, or rule relevant to the practice of medicine or podiatric medicine, whichever is applicable, and may inspect documents relevant to those investigations in accordance with the following procedures:
- (1) Any document relevant to an investigation may be inspected, and copies may be obtained, where patient consent is given.
- (2) Any document relevant to the business operations of a licensee, and not involving medical records attributable to identifiable patients, may be inspected and copied if relevant to an investigation of a licensee.
- (c)(1) Notwithstanding subdivision (b) or any other law, in any investigation that involves the death of a patient, the board may inspect and copy the medical records of the deceased patient without the authorization of the beneficiary or personal

representative of the deceased patient or a court order solely for the purpose of determining the extent to which the death was the result of the physician and surgeon's conduct in violation of the Medical Practice Act, if the board provides a written request to either the physician and surgeon or the facility where the medical records are located or the care to the deceased patient was provided, that includes a declaration that the board has been unsuccessful in locating or contacting the deceased patient's beneficiary or personal representative after reasonable efforts, or that the patient's beneficiary or personal representative have not served the board with a written objection within 15 days of the board's request. Nothing in this subdivision shall be construed to allow the board to inspect and copy the medical records of a deceased patient without a court order when the beneficiary or personal representative of the deceased patient has been located and contacted but has refused to consent and has served a written objection on the board within 15 days of the board's request to the board inspecting and copying the medical records of the deceased patient.

- (2) The Legislature finds and declares that the authority created in the board pursuant to this section, and a physician and surgeon's compliance with this section, are consistent with the public interest and benefit activities of the federal Health Insurance Portability and Accountability Act (HIPAA).
- (d) Where patient consent is not given, an investigator with the board or the Department of Consumer Affairs, Health Quality Investigation Unit, with or without the assistance of a medical consultant at the investigator's discretion, may inspect patient records in the office of the licensee for the limited purpose of determining whether good cause exists to support an investigative subpoena for such records.
- (de) In all cases in which documents are inspected or copies of those documents are received, their acquisition or review shall be arranged so as not to unnecessarily disrupt the medical and business operations of the licensee or of the facility where the records are kept or used.
- (ef) If documents are lawfully requested from licensees in accordance with this section by the Attorney General or his or hertheir agents or deputies, or investigators of the board or the California Board of Podiatric Medicine, the documents shall be provided within 15 business days of receipt of the request, unless the licensee is unable to provide the documents within this time period for good cause, including, but not limited to, physical inability to access the records in the time allowed due to illness or travel. Failure to produce requested documents or copies thereof, after being informed of the required deadline, shall constitute unprofessional conduct. The board may use its authority to cite and fine a physician and surgeon for any violation of this section. This remedy is in addition to any other authority of the board to sanction a licensee for a delay in producing requested records.
- (fg) Searches conducted of the office or medical facility of any licensee shall not interfere with the recordkeeping format or preservation needs of any licensee necessary for the lawful care of patients.

Obtaining pharmacy records in a timely manner. HQIU and MBC staff may experience months-long delays obtaining pharmacy records, as the law does not provide a clear and definite timeframe for pharmacies to turn over their records to investigators. BPC Section 4081 requires a pharmacy to maintain various records for a period of at least three years and make them available for inspection to authorized officers of the law within business hours. BPC Section 4332 states that any person who fails, upon request by an authorized person, to produce or provide pharmacy records within "a reasonable time" is guilty of a misdemeanor. MBC

investigators indicate that a reasonable time standard is vague and difficult to enforce, sometimes leading to a lengthy delay to receive necessary records. MBC believes that BPC section 4081 should be amended to include a time-bound deadline so that its investigators may obtain pharmacy records without needless delays.

Statutes of limitations. Under current law, when a licensee refuses to produce medical records pursuant to a lawfully- issued and patient-noticed investigative subpoena, MBC is required to litigate a petition for subpoena enforcement in superior court. BPC section 2225.5(b)(1) currently reads:

(b)(1) A licensee who fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board shall pay to the board a civil penalty of one thousand dollars (\$1,000) per day for each day that the documents have not been produced after the date by which the court order requires the documents to be produced, up to ten thousand dollars (\$10,000), unless it is determined that the order is unlawful or invalid. Any statute of limitations applicable to the filing of an accusation by the board shall be tolled during the period the licensee is out of compliance with the court order and during any related appeals.

MBC reports that during this often lengthy process, the statute of limitations continues to run on the stalled underlying investigation of the subject. The statute does not begin to toll unless and until the licensee fails to produce the subpoenaed records by the deadline set by the court, after granting MBC's enforcement petition. Moreover, MBC says the delay to the process is compounded because MBC's subpoena enforcement matters are not entitled to be given priority by the courts. As a result, licensees and their counsel have every incentive to draw out the subpoena enforcement litigation, thereby delaying the production of needed evidence in the underlying investigation. Case law allows physicians to argue on behalf of the patient's privacy interests even though, as MBC notes, there is misalignment, and outright conflict, with the MBC public protection interests. Even when MBC proceeds at the quickest pace possible to obtain a superior court order compelling production, investigations are often severely delayed while MBC litigates subpoena enforcement matters, sometimes leaving very little time to fully develop an investigation, obtain expert review of the subpoenaed records, and draft and file an accusation. As an example, in the past four fiscal years, the DOJ, Civil Division, Health Quality Enforcement Section has filed 24 subpoena matters in superior court on behalf MBC, and eight of those matters have gone up on appeal. MBC notes that while the number of subpoena enforcement cases relative to the total number of accusations filed in a fiscal year is small, the time and expense is great.

MBC believes that for the purposes of public protection and for evidence and resource preservation, the date of the superior court's issuance of the order to show cause would be an appropriate time to toll the statute of limitations. MBC would still have a strong incentive to promptly bring its subpoena enforcement actions, but having brought such an action, any delays in the litigation would not benefit either party, and the respondent licensee will not be able to use the subpoena enforcement action to their advantage to try to run out the statute of limitations.

Accordingly, the Board proposes amending BPC section 2225.5(b)(1) to read as follows:

(b)(1) A licensee who fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the board shall pay to the board a civil penalty of one thousand dollars (\$1,000) per day for each day that the documents have not been produced after the date by which the court order requires the documents to be produced, up to ten thousand dollars (\$10,000), unless it is determined that the order is unlawful or invalid. Any statute of limitations applicable to the filing of an accusation by the board shall be tolled upon the service of an order to show cause pursuant to Government Code section 11188, until such time as the subpoenaed records are produced, including any period the licensee is out of compliance with the court order and during any related appeals, or until the court declines to issue an order mandating release of records to the board.

<u>Staff Recommendation:</u> The Committees may wish to amend the Act to ensure MBC has the necessary tools to take swift action.

ISSUE #20: (ENFORCEMENT DISCLOSURES.) MBC licensees are required to disclose probationary status to patients and MBC makes this available public on its website and through other means. How has the implementation of the Patient's Right to Know Act enhanced consumer awareness with MBC and licensees? Has MBC seen any changes in its disciplinary proceedings stemming from the disclosure requirement that impacts an extremely small number of MBC licensees?

<u>Background:</u> Access to timely, accurate information about MBC licensees is a fundamental means by which patients and the public are informed about medical services provided to them. MBC posts information on its website and has improved these efforts. The Legislature has also responded to significant gaps in the ability for patients to have full awareness of disciplinary action taken against their physician. Information posted to a licensee's profile and provided to the public is specifically set forth in statute. In 2018, the Legislature passed the Patient's Right to Know Act (SB 1448, Hill, Chapter 570, Statutes of 2018) which required physicians ordered on probation to proactively notify patients of their status and required MBC to add a probation summary to the profile pages of physicians on probation for acts of serious misconduct.

MBC's website provides the following information about physicians:

- Discipline taken by MBC (public reprimands and public letters of reprimand are only available for ten years on the website).
- Formal accusations by MBC of wrongdoing.
- Practice restrictions or practice suspensions pursuant to a court order.
- Discipline taken by a medical board of another state or federal government agency.
- Felony convictions MBC has reports of (for convictions after January 3, 1991).
- Misdemeanor convictions (for convictions after January 1, 2007) that resulted in a disciplinary
 action or an accusation being filed by MBC if the accusation is not subsequently withdrawn or
 dismissed.

- Citations received for a minor violation of the Act within the last three years (for citations that have not been withdrawn or dismissed).
- Public letter of reprimand issued at time of licensure within the last three years.
- Any hospital disciplinary actions that resulted in the termination or revocation of the physician's privileges to provide health care services at a healthcare facility for a medical disciplinary cause or reason reported to MBC after January 1, 1995.
- All malpractice judgments and arbitration awards reported to MBC after January 1, 1998 (between January 1, 1993 and January 1, 1998, only those malpractice judgments and arbitration awards more than \$30,000 were required to be reported to MBC).
- All malpractice settlements over \$30,000 reported to MBC after January 1, 2003 that meet certain criteria.

<u>Staff Recommendation:</u> MBC should provide an update on the implementation of the Patient Right to Know Act.

<u>ISSUE # 21:</u> (DISPARITY IN ENFORCEMENT ACTIONS.) MBC commissioned a third-party study to identify whether disparity in its enforcement actions were present. Do problems still exist?

<u>Background:</u> In response to concerns raised by members of the African American physician community and a formal request from the Golden State Medical Association (GSMA), MBC previously contracted with the California Research Bureau (CRB) to conduct a study aimed at determining if disparity exists in MBC's enforcement efforts. MBC is required to collect certain demographic information from licensees on a voluntary basis. According to MBC, about 70 percent of licensees voluntarily provide this information.

CRB's study was released in 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 black physicians were both more likely to receive 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 the 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.

MBC formed a Disciplinary Demographic Study Task Force to further explore this issue and provide additional direction to MBC. MBC also noted that it would promptly begin training for members and all staff to ensure equity in its work. In September 2017, the Board held in-person implicit bias trainings for 298 employees of the Board, HQIU, Deputies Attorney General, and Board Members. MBC produced a webinar version of the training in 2019 and required the training be competed every two years. Board staff are encouraged to participate in other training on this topic, as well.

MBC implemented a policy to remove information from documents submitted to expert reviewers, and in the stipulation memos submitted to Board Members for review in licensing and disciplinary cases that is not essential to the evaluation of the matter, but that could trigger unconscious or implicit bias relating to race, ethnicity, or other factors, including where the person went to school, where they completed postgraduate training, and whether they are board certified by a specialty board. MBC notes that addressing implicit bias requires steadfast commitment at every level, and advises that it will continue to look for and implement new approaches to training, as well as reviewing, investigating, and determining case outcomes in a manner that reduces the influence of unconscious bias.

<u>Staff Recommendation:</u> MBC should provide an update to the Committees on its efforts to ensure that bias and disparities do not exist in any of its programs. MBC should establish a formal policy against racial discrimination.

ISSUE # 22: (ENFORCEMENT DELAYS.) Previsouly, MBC's investigations were simultaneously assigned to an investigator and a DAG in a system called vertical enforcement (VE). VE was ended in 2019; yet even with the removal of the statutory VE provisions, the timeframe for investigating cases has increased from 467 days in FY 2016/17, to 510 days in FY 2017/18, 547 days in FY 2018/19, and 548 days in FY 2019/20. The issue of the quality of investigations, and enforcement timelines, is a problem that the Legislature has attempted to solve through numerous reviews of MBC, investigator, and OAG activities, yet enforcement delays remain and public protection remains threatened by the lack of swift action against violating licensees.

Background: Following the 2004 release of a statutorily mandated report by an independent enforcement program monitor, MBC implemented a vertical prosecution model, or MBC's Vertical Enforcement Prosecution (VE). VE required DAGs to be involved in MBC's investigation activities as well as its prosecution activities (DAGs serve as the attorneys of record to DCA licensing boards and are responsible for initiating and taking legal steps for administrative disciplinary action against the holder of a professional license). Through VE, DAGs and HQIU investigators were jointly assigned to an investigation from the outset. This team approach was intended to encourage early coordination and faster decisions, filings, and results given that true VE allows a prosecutor to learn a case as it is being built and in theory allows the DAG to assist in securing medical records, physician interviews, select expert witness and other critical elements of a successful case. VE differed from the process used by other boards within DCA – other boards typically conduct investigations with their own enforcement staff or DOI and then forward those investigations and cases to DAGs for appropriate administrative filings. The initial report by the enforcement monitor (Monitor's Report) called for MBC investigators to be transferred from MBC to OAG's Health Quality Enforcement (HQE) section which prosecutes MBC cases.

Despite VE and other enhancements, MBC's enforcement activities were still called into question during prior reviews of MBC. MBC was seen as continuing to fail to aggressively investigate and pursue actions against dangerous physicians. In response, SB 304 of 2013 again proposed the transfer of MBC investigators to HQE but ultimately required MBC to instead transfer its investigators to DCA's DOI, establishing the framework for the current HQIU. DOI and OAG worked to establish formal policies and procedures for VE following the transfer of investigators to DOI as of July 1, 2014. In July 2015, the VE Prosecution Protocol manual was finally formalized, providing guidelines for staff members conducting investigations and strategies to resolve disagreements between

investigators and HQE DAGs. The manual also outlined cooperation and communication expectations between the two offices. According to internal surveys conducted among investigators within HQIU, many investigators resented any implication that their work required supervision or control by OAG attorneys. Claims of low morale within HQIU were generally supported by persistent vacancy rates and high turnover. The manual emphasized collaboration and conflict resolution between HQIU and HQE, stemming from strained personnel issues between the two offices. The manual sought to address disagreements by providing clarified definitions regarding the roles of each office and the expected amounts of direction and supervision HQE should provide HQIU. For example, the manual included a clarification that DAGs directed investigations but not the investigators themselves.

Yet problems still persisted and MBC enforcement timelines continued to grow.

The initial intent and structure of the VE model did not appear to be upheld, as cases were being conducted with the "handoff method". The entire purpose of the VE model was to eliminate this handoff method by aligning investigators and legal staff to handle cases together, instead of the traditional route of investigator gathering information and "handing" the case off to legal staff. With high levels of staff turnover in HQIU and shifting assignments in HQE, cases were not handled by the same investigator and same DAG from start to finish.

A March 2016 MBC report on VE showed that MBC spent \$18.6 million to implement the program and provided statistical data showing that the average investigation timeframe increased. In 2019, statutory requirements for VE were repealed pursuant to SB 798.

Cases that continue to languish result in public harm. MBC just filed an accusation to revoke the license of a pediatrician who had been accused of sexual abuse for years. The physician had been the subject of a civil lawsuit filed on behalf of a former foster youth who alleged the physician had sexually abused them; the physician was removed from a position as chief county pediatrician after the District Attorney's Office found substantial evidence the physician committed multiple crimes of moral turpitude, specifically sexual assaults; and the physician was prohibited by a state agency from working with any children or adults in state-licensed facilities. The physician is still in practice and will remain in possession of a current license for years before the case is resolved.

It would be helpful for the Committees to understand what happens today and how complex cases that require collaboration are undertaken. It would be helpful for the Committees to know the status of the working relationship between MBC, HQIU, and HQE, and what statutory improvements may be necessary to ensure cases are investigated and prosecuted well in a timely manner.

MBC is concerned that timeframes are still delayed due to the fact that investigators are housed within HQIU rather than MBC. According to MBC, once it transmits a case to HQIU, it no longer has direct oversight of the investigation, yet MBC is held accountable for the results. In most cases, it is not until the investigation is complete, and an expert reviewer has opined on the investigation, that the case is returned to the MBC for review. Sometimes, for a variety of reasons, the investigations must be sent back to the field for additional investigatory work, which further delays the cases. Following the initial move of the MBC's investigators to HQIU, MBC experienced a significant increase in enforcement timeframes. MBC transfers most complaints that require additional investigation to HQIU and remains responsible for reviewing the outcome of the investigation for approval, however day-to-day management and direction of the investigation process is handled by DCA and outside MBC's oversight.

MBC states that prior to transferring MBC investigative staff to the HQIU, the median days to investigate a physician and surgeon complaint was 205 days in FY 2013/14. Just one year later, the median days for the HQIU to investigate a physician and surgeon complaint increased to 349 days in FY 2014-15, an increase of 72 percent (144 days). The median number of days for the HQIU to investigate a complaint have increased by 43 percent from 349 days in FY 2014/15 to 502 days in FY 2018/19. Since moving the Board investigators to HQIU, this increase to 502 days has more than doubled the timeframes from 205 days in FY 2013/14.

MBC says that the costs associated with investigations have also increased significantly. In recent years, MBC has seen substantial cost increase for HQIU and expects these cost increases to continue during the next few years. HQIU expenses have increased by 20 percent from \$16.4 million in FY 2014/15 to \$19.6 million in FY 2018/19. MBC expects the HQIU staff salary and benefit expenses to increase by an additional 44 percent from \$19.6 million in FY 2018/19 to \$28.3 million in FY 2024/25.

Regardless of whether statute requires a formal VE program and notwithstanding where investigator positions are housed, it is essential that clear and consistent communication take place between investigators and prosecutors of cases brought by MBC. Given the clear remaining issues with MBC cases being adjudicated in an appropriate timeframe, coupled with the significant impact increased rates for DAG services on MBC's budget, it may be time to review whether MBC cases should continue to be prosecuted by OAG or if an alternative path exists. It would be helpful for the Committees to understand the cost savings, value, and positive patient impacts that could arise from MBC investigating and prosecuting its own cases.

<u>Staff Recommendation:</u> Now that VE has been repealed, MBC should explain whether it believes there has been any positive changes from a process perspective and whether relationships between HQIU and HQE have improved. The Committees may wish to consider whether any proposed transfer of HQIU's investigators would result in any benefit to enforcement timelines or produce more successful prosecutions.

ISSUE #23: (OVERPRESCRIBING AND THE OPIOID CRISIS.) Growing efforts to combat the opioid crisis from a public health approach have brought attention to the important role physicians and other prescribers play in identifying patients who pose a risk for abusing or diverting controlled substances. How has MBC furthered these efforts through its role as a regulator of physicians and surgeons?

Background: In October of 2017, the White House declared the opioid crisis a public health emergency, formally recognizing what had long been understood to be a growing epidemic responsible for devastation in communities across the country. According to the Centers for Disease Control and Prevention (CDC), as many as 50,000 Americans died of an opioid overdose in 2016, representing a 28 percent increase over the previous year. Additionally, the number of Americans who died of an overdose of fentanyl and other opioids more than doubled during that time with nearly 20,000 deaths. These death rates compare to, and potentially exceed, those at the height of the AIDS epidemic.

Opioids are a class of drugs prescribed and administered by health professionals to manage pain. Modern use of the term "opioid" typically describes both naturally occurring opiates derived from the opium poppy as well as their manufactured synthetics. Common examples of prescription opioids include oxycodone (OxyContin, Percocet); hydrocodone (Vicodin, Norco, Lorcet); codeine; morphine; and fentanyl. Heroin is also an opioid.

In addition to providing pain relief, opioids can be used as a cough suppressant, an antidiarrheal, a method of sedation, and a treatment for shortness of breath. The majority of pharmaceutical opioids are Schedule II drugs under the federal Controlled Substances Act, considered by the federal Drug Enforcement Agency (DEA) to have a high potential for abuse that may lead to severe psychological or physical dependence. However, combination drugs containing lower doses of opioids combined with other active ingredients are typically less restricted; for example, cough syrups containing low doses of codeine are frequently classified Schedule V medications.

The abuse of prescription drugs was historically viewed as a criminal concern analogous to street narcotics cases regularly investigated by law enforcement. In recent years, however, an expert consensus has evolved around the opinion that the opioid crisis must be addressed through the lens of public health policy. This belief is supported by research demonstrating how health professionals may have inadvertently contributed to the origins of the crisis. It is widely accepted that health professionals will play a critical role in any meaningful solutions.

In November 2014, MBC released its *Guidelines for Prescribing Controlled Substances for Pain*. These guidelines were intended to "help physicians improve outcomes of patient care and prevent overdose deaths due to opioid use." The guidelines contained a number of recommendations, including that physicians consult with addiction medicine specialists, create a written treatment plan and patient agreement, and "use a non-judgmental approach" to discussing potential misuse or abuse with patients.

MBC's guidelines also recommended that physicians "exhaust all non-opioid pain management methodologies prior to considering opioid therapy." In 2017, the American College of Physicians (ACP) published updated guidelines in the Annals of Internal Medicine, summarizing the results of studies related to the use of noninvasive methods for treating low back pain in adults. The ACP described studies indicating that effective treatment options include acupuncture and spinal manipulation. The ACP also describes how studies show that "before taking medicines, patients with chronic low back pain should try other treatments" including "therapy that addresses physical, psychological, and social issues that may be causing pain," acupuncture, and behavioral health. The ACP states that "opioids should be considered only if no other treatments work and only if there are more benefits than risks for an individual patient."

In reviewing the effectiveness of nonpharmacological therapies, the CDC also concluded that "nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate." While efforts have not been successful to require physicians to refer patients to nonopioid pain management treatment options, MBC may still consider steps to encourage or require physicians to incorporate nonopioid treatments as part of the standard of care.

MBC's guidelines also recommended that physicians regularly consult the state's prescription drug monitoring program (PDMP), known as CURES. CURES was first established in 1996 as a "technologically sophisticated" database containing prescription records collected through California's Triplicate Prescription Program, which provided the DOJ with copies of all Schedule II drug prescriptions. Subsequent legislation made CURES the state's sole prescription record repository and added Schedule III and IV drugs to the database. In 2008, CURES was upgraded to function as a

PDMP, allowing health professionals, regulators, and law enforcement to conduct web-based searches of the system to inform prescribing practices and support investigations.

Every dispenser of controlled substances and every health practitioner authorized by the DEA to prescribe controlled substances is required to obtain a login for access to CURES. For each dispensed Schedule II, III, IV, or V drug, pharmacists are required to report basic information about the patient and their prescription. This information is then made available to other system users in a variety of possible contexts. For example, physicians may query a patient's prescription history prior to writing a new prescription; pharmacists can check the system before agreeing to fill a prescription for a controlled substance; regulators may review a licensee's prescribing practices as part of a disciplinary investigation; and law enforcement can incorporate a search of the system into a potential criminal case of drug diversion.

As of October 2018, health practitioners are required to consult the CURES database prior to writing a prescription for a Schedule II, III, or IV drug for the first time, and then at least once every four months as long as the prescription continues to be renewed. Other recently enacted statutes require the DOJ to facilitate interoperability between health information technology systems and the CURES database, subject to a memorandum of understanding setting minimum security and privacy requirements. As attention to the opioid crisis continues to grow, CURES and other PDMPs are regularly mentioned as powerful tools for curbing the abuse of prescription drugs.

MBC is required to enforce the CURES query mandate as part of its oversight functions. MBC may also use CURES as part of its own investigations into prescribing practices among licensees. As efforts to address the overprescribing epidemic persist, MBC should continue to identify ways to utilize the system in its efforts to prevent opioid abuse and overdose deaths.

<u>Staff Recommendation:</u> MBC should provide the Committees with insight into how it has helped to combat the opioid crisis through its oversight of physicians and surgeons and whether it believes any further statutory change would better enable CURES to function principally as a public health tool.

COVID-19

ISSUE #24: (IMPACTS OF THE COVID-19 PANDEMIC.) Since March 2020, there have been a number of waivers issued through Executive Orders that impact MBC operations, MBC licensees, providers, and patients throughout the state. Do any of these waivers warrant an extension or statutory changes? How has the MBC addressed issues resulting from the pandemic?

Background: In response to the COVID-19 pandemic, a number of actions were taken by the Governor, including the issuance of numerous executive orders in order to address the immediate crisis. Many executive orders directly impact the state's healthcare workforce. On March 4, 2020, the Governor issued a State of Emergency declaration which immediately authorized the Director of the Emergency Medical Services Authority (EMSA) to allow licensed healthcare professionals from outside of California to practice in California without a California license. Under BPC Section 900, licensed professionals are authorized to practice in California during a state of emergency declaration as long as they are licensed and have been deployed by the Director of EMSA. Following that executive order, on March 30, 2020, the Governor issued Executive Order N-39-20 authorizing the

Director of DCA to waive any statutory or regulatory professional licensing relating to healing arts during the duration of the COVID-19 pandemic – including rules relating to examination, education, experience, and training.

Many of the waivers impact MBC's work and MBC licenses. For example, <u>Executive Order N-40-20</u> permits the Director of DCA to waive any statutory or regulatory requirements with respect to CE a number of healing arts licensees. MBC noted in its 2020 Sunset Review Report, that it worked with DCA on the following waivers:

Postgraduate Training License

<u>DCA Waiver DCA-20-50 Postgraduate Training License Deadline.</u> The order waives the requirements to obtain a PTL by June 30, 2020, for individuals who were enrolled in an approved postgraduate training program in California on January 1, 2020. Individuals must obtain a PTL on or before October 31, 2020, unless the waiver is extended. <u>DCA Waiver DCA-20-93</u> extended this deadline until March 31, 2021.

Many schools closed or relocated staff due to COVID-19, which created challenges for applicants to obtain documentation required for licensure. At the onset of the pandemic, many fingerprint Livescan facilities were also closed, further delaying applicants' abilities to meet licensure requirements. This waiver provided additional time to allow applicants to meet licensure requirements.

DCA Waiver DCA-20-100 Postgraduate Training License Deadline. The order extends the 180-day deadline for individuals initially enrolled in an approved postgraduate training program between June 1, 2020 and July 31, 2020 to obtain a PTL. Individuals must obtain a PTL on or before March 31, 2021, unless the waiver is extended.

Many schools closed or relocated staff due to COVID-19, which created challenges for applicants to obtain documentation required for licensure. At the onset of the pandemic, many fingerprint Livescan facilities were also closed, further delaying applicants' abilities to meet licensure requirements. This waiver provided additional time to allow applicants to meet licensure requirements.

Physician's and Surgeon's License

DCA Waiver DCA-20-65 Physician's and Surgeon's License Deadline. This order extended the deadline to December 31, 2020, for individuals who completed at least 36 months of approved postgraduate training outside of California, were enrolled in an approved postgraduate training program in California on July 1, 2020, and who are required to obtain a physician's and surgeon's license from the Board within 90 days to continue the practice of medicine, pursuant to BPC section 2065, subdivision (h). DCA Waiver DCA-20-94 further extended this deadline to March 31, 2021.

These applicants experienced the similar challenges as the PTL applicants in obtaining required documents for licensure. This waiver provided additional time to allow applicants to meet licensure requirements.

Physician Supervision of Nurse-Midwives, Physician Assistants, and Nurse Practitioners

DCA Waiver DCA-20-04 waives the supervision requirements and allows physicians to supervise more than four PAs at one time. Further, it waived other supervision requirements if (1) a PA moves to a practice site or organized health care system to assist with the COVID-19 response, but does not have a practice agreement in place with any authorized physician of the site or system; or (2) as a result of the COVID-19 response, no supervising physician with whom a PA has an enforceable practice agreement is available to supervise the PA.

<u>DCA Waiver DCA-20-05.</u> Waives supervision requirements and allows a physician to supervise more than four nurse practitioners at any one time when furnishing or ordering drugs or devices.

<u>DCA Waiver DCA-20-06 Nurse-Midwife Supervision Requirements.</u> Waives supervision requirements and allows physicians to supervise more than four certified nurse-midwives at one time.

The initial waivers relating to nurse-midwives, PAs, and nurse practitioners have been extended several times. DCA Waiver DCA-20-83, terminates on February 8, 2021.

Examination Requirements

<u>DCA Waiver DCA-20-25 Extending Time to Satisfy Examination Requirements.</u> The order extends the timeframe for when a physician and surgeon application is deemed abandoned due to the applicant failing to pass or retake Step 3 of the USMLE from 12 months to 18 months from the date of notification by the Board. This order supports applicants unable to complete this necessary licensing examination during the COVID-19 pandemic. This waiver was expanded by <u>DCA Waiver DCA-20-66</u>.

License Renewal

<u>DCA Waiver DCA-20-53 Waiving Licensing Renewal Requirements.</u> This order temporarily defers the CME renewal requirement for licenses that expire between March 31, 2020 and October 31, 2020 for six months after the date of the waiver. Licensees must satisfy CE requirements within six months unless the waiver is extended. <u>DCA Waiver DCA-20-69</u> further extended the deadline another six months until April 22, 2021.

Many CME providers were forced to close or halt services due to the pandemic, which prevented licensees from meeting renewal requirements. This waiver provides additional time for licensees to obtain the required CME while providers adapt to alternate methods of providing these courses.

License Restoration

DCA Waiver DCA-20-57 Restore Inactive, Retired, or Cancelled License

This order allows licensees to temporarily restore an inactive or retired license without having to pay any fees or complete, or demonstrate compliance with, any CE requirements until January 1, 2021, or when the State of Emergency ceases to exist, whichever is sooner. A licensee with a cancelled status that was voluntarily surrendered within the last five years not

relating to a disciplinary action may meet the waiver criteria as well. As noted by the MBC, this waiver supported the state's COVID-19 pandemic response by increasing the availability of licensed health care professionals to treat patients.

MBC advises that all of the above-mentioned waivers were improved and implemented. While many have dates ending within the early months of 2021, it is unclear if any will be further extended or retired and what, if any, impact will be on the MBC's workload.

In addition to the use of waivers, MBC notes that it altered the requirements to obtain a PTL. Due to the USMLE suspending Step 2 CS for 12-18 months due to the pandemic, the MBC no longer requires passage of Step 2 CS to obtain a PTL. The online and hard copy applications were updated to reflect these changes.

In addition to the use of waivers and programmatic changes, MBC additionally notes that many staff are telecommuting on either a full- or part-time basis. Most of the staff working in the office are on a staggered work shift to reduce the number of staff in the office at the same time. In order to accommodate teleworking by a majority of staff, processes and workflows have been adjusted, modified and readjusted. The lack of a paperless platform created a unique series of challenges; however, MBC notes that staff has been flexible to ensure MBC continues to meet its mandate. To address COVID-19 concerns, MBC moved quarterly board meetings from an in-person format to an online format through the WebEx platform. MBC reports that it will continue to utilize remote meetings until the State of Emergency is lifted.

Regarding enforcement and investigations, MBC notes that is has modified its activities to incorporate video or telephonic means for conducting interviews and probation updates. Additionally, systems for sharing information with HQIU and the AGO have been shifted to electronic means. That MBC notes some challenges resulting from the pandemic as courts and county offices have been closed or are on very limited hours of operation, so obtaining information or documentation has been difficult and at times, not possible. In addition, the OAH was closed for a period of time beginning in March 2020 but began operations and started holding hearings by remote means in late summer.

Telehealth is a tool that allows for patient care without the provider and patient being in the same physical location, a critical option for physicians and patients in light of the COVID-19 pandemic. COVID-19 has placed an emphasis on telehealth services. Individuals using telehealth technologies to provide care to patients located in California must be licensed in California. Pursuant to BPC Section 2290.5, licensees are held to the same standard of care, and retain the same responsibilities of providing informed consent, ensuring the privacy of medical information, and any other duties associated with practicing medicine, regardless of whether they are practicing via telehealth or face-to-face, in-person visits. It is likely that most MBC licensees will have to adopt at least some form of telehealth services in order to serve patients. This in turn requires telehealth services to be regulated and overseen in order to ensure quality in the same way oversight of in-person examinations is expected. Without ensuring physicians and surgeons are following the standard of care in every practice setting, California patients can be put at risk.

Telehealth includes several components, one of which is online practice. As technology advances, MBC needs to remain aware about situations where physicians are not complying with telehealth laws and not following the standard of care in providing services to patients. MBC reports that one of the most frequent violations involves physicians and surgeons treating California patients via telehealth

from another state without having a California license. In the past, complaints regarding telehealth were not prevalent. However, as technology advanced over the last few years, more complaints have been received regarding care provided via telehealth, including complaints of unlicensed practice, inappropriate care, and the corporate practice of medicine. With future advances in technology, including applications available on electronic devices and more, this will continue to be an issue that the MBC notes it needs to be vigilant about to ensure consumer protection. Complaints about care received through telehealth follow the same investigative and prosecutorial process as all other complaints; MBC notes it has seen an increase in the number of complaints regarding the use of telehealth, including the online aspect of telehealth.

In response to the question of whether or not any of the waivers or MBC operational changes stemming from the pandemic should be continued or extended indefinitely, MBC notes that a change to the open meeting requirements to continue authorization for the use of online meetings would save MBC both money and time. In addition, continued online meetings will protect Board members, staff, and the public when dangerous conditions arise without the need to wait for an executive order permitting the use via an online platform.

<u>Staff Recommendation:</u> MBC should update the Committees on the impact to licensees and patients stemming from the pandemic and potential challenges for future physicians and surgeons. MBC should discuss any statutory changes that are warranted as a result of the pandemic.

TECHNICAL CHANGES

ISSUE #25: (TECHNICAL CHANGES MAY IMPROVE EFFECTIVENESS OF THE MEDICAL PRACTICE ACT AND MBC OPERATIONS.) There are amendments to the Act that are technical in nature but may improve MBC operations and the enforcement of the Medical Practice Act.

<u>Background:</u> There are instances in the Medical Practice Act where technical clarifications may improve MBC operations and application of the statutes governing MBC's work.

<u>Staff Recommendation:</u> The Committees may wish to amend the Act to include technical clarifications.

<u>CONTINUED REGULATION OF PHYSICIANS AND SURGEONS, LICENSED</u> <u>MIDWIVES AND VARIOUS OTHER HEALTH PROFESSIONALS BY</u> THE MEDICAL BOARD OF CALIFORNIA

<u>ISSUE #26:</u> (CONTINUED REGULATION BY MEDICAL BOARD OF CALIFORNIA.) Should the licensing and regulation of physicians and surgeons, licensed midwives and other allied health professionals be continued and be regulated by the current MBC membership?

Background: Patients and the public are best protected by a strong regulatory board with oversight for physicians and surgeons and associated allied professions. Physicians remain among the most highly trusted professions, as demonstrated in national patient surveys, and millions of Californians receive quality care from MBC licensees every day. While the percentage of licensees who are subject to formal discipline is small in comparison to the large number of licensees, the cost to patients and the public is incredibly high when MBC enforcement stalls. Balancing swift, patient-centered action with

appropriate due process that all licensees must be afforded remains key to ensure MBC does its job. An evaluation of the alternatives to status quo must take place in order to promote patients and the public when determining necessary reforms to the Act and MBC operations.

<u>Staff Recommendation</u>: The MBC should be continued, to be reviewed again on a future date to be determined.