# CURRENT SUNSET REVIEW ISSUES FOR THE MEDICAL BOARD OF CALIFORNIA - 2013

### LICENSING, EXAMINATION AND PRACTICE ISSUES

<u>ISSUE #1</u>: (AB 2699 Implementation: Out-of-State Physicians Providing Free Health Care Services.) How many physicians and surgeons have been exempted from licensure pursuant to AB 2699?

**Background:** AB 2699 (Bass, Chapter 270, Statutes of 2010) exempts from California licensure specified health care practitioners who are licensed or certified in other states and who register with the board and who provide health care services on a voluntary basis to uninsured or underinsured persons in California, as specified.

The MBC states that it was the first board within DCA to enact regulations to implement these provisions set forth in BPC § 901. The regulations allow physicians who are licensed, but not in California, to participate in sponsored free health care events. The regulations provide the rules and documents for registration of sponsored free health care events and the physicians who volunteer their services. Physicians must hold a license in good standing in another state to register.

At the time of the writing of the Sunset Report, the MBC stated that since the regulations only became effective in August 2012, that no applications had yet been received.

<u>Staff Recommendation</u>: The MBC should inform the Committee how many physicians and surgeons have been exempted from licensure pursuant to the regulations adopted to implement AB 2699.

### MBC Response (April 2013):

AB 2699 added Business and Professions Code Section 901 (B&P Section 901), which provided a framework under which a health care practitioner licensed and in good standing in another state, may provide health care services for a limited time in California without obtaining California licensure, under specified circumstances. These professional services can only be provided at free health care events sponsored by certain approved entities. Although AB 2699 became effective in 2011, the program could not be implemented until regulations were in place. The Medical Board of California (MBC) adopted regulations that became effective on August 20, 2012. The Board received one and approved one application for an individual to attend an event in April 2013.

## <u>ISSUE #2</u>: Is a statutory change needed to accommodate changes to the United States Medical Licensing Examination?

**Background:** In its Sunset Report, the MBC has raised the following new issue. Individual state medical boards set their own rules, regulations and requirements for passage of examinations to demonstrate an applicant's qualifications for medical licensure. In California, the MBC receives examination results from the United States Medical Licensing Examination

(USMLE) program, which is used to determine if an individual will be granted licensure to practice medicine in California.

The examination consists of three steps, which must be passed sequentially in order to be eligible to move on to the next examination step. The steps are defined as:

- Step 1: Focuses primarily on understanding and application of key concepts of basic biomedical sciences.
- Step 2: Focuses primarily on knowledge, skills, and understanding of clinical science that forms the foundation for safe and competent supervised practice.
- Step 3: Focuses primarily on the knowledge and understanding of the biomedical and clinical science essential for the unsupervised, general practice of medicine.

The evolution of medical advancements as well as shifts in medical practice and education, have required changes to the format delivery and content of the examinations. However, the original three-step concept remains intact. In 1999, a major change was made to the examination format delivery, which transitioned from paper-based delivery to computer delivery. In 2004, a standardized patient examination was introduced as a component of Step 2. However the focus and overall structure of the step examinations have remained relatively unchanged.

The USMLE Composite Committee and its parent organizations, the Federation of State Medical Boards (FSMB), and the National Board of Medical Examiners (NBME), have approved plans to change the structure of the USMLE. Step 3 is slated to be the first examination impacted. The USMLE has stated the changes to Step 3 will "occur no earlier than 2014". The plans call to divide Step 3 into two separate exams, one day in length each, and will focus on different sets of competencies. The two examinations will be scored separately and applicants must pass each. There may also be new testing formats to focus on competencies not currently addressed in Step 3. Step 3 of the USMLE will remain known as Step 3; however, it will be a two-part examination.

The MBC states that BPC § 2177 (c) may require legislative change to ensure the new testing format is addressed.

### BPC § 2177

- (a) A passing score is required for an entire examination or for each part of an examination, as established by resolution of the Board.
- (b) Applicants may elect to take the written examinations conducted or accepted by the Board in separate parts.
- (c)(1)An applicant shall have obtained a passing score on Step 3 of the United States Medical Licensing Examination within not more than 4 attempts in order to be eligible for a physician's and surgeon's certificate.
- (2) Notwithstanding paragraph (1), an applicant who obtains a passing score on Step 3 of the United States Medical Licensing Examination in more than 4 attempts and who meets the requirements of section 2135.5 shall be eligible to be considered for issuance of a physician's and surgeon's certificate.

MBC points out, that Board regulations may also require changes to ensure aspects of the new testing steps are addressed.

The MBC recommends that the language of BPC § 2177 be amended to accommodate two parts of the Step 3 examination, and any new evolving examination requirement.

<u>Staff Recommendation</u>: The MBC should submit to the Committee specific language to amend BPC § 2177 to accommodate two parts to Step 3 of the USMLE, and to accommodate future examination changes.

### MBC Response (April 2013):

Language was submitted on March 5, 2013 to Senate Business, Professions, and Economic Development (B&P) Committee staff that would amend Business and Professions Code section 2177 to accommodate two parts for Step 3 of the United States Medical Licensing Examination.

<u>ISSUE #3</u>: (Physician Shortages Anticipated.) Should changes be made to allow Medical School Programs to utilize Accelerated 3-Year and Competency-Based Medical School Programs?

**Background:** The MBC has raised the following as a new issue in its Sunset Report. A nationwide physician shortage is projected to reach 90,000+ physicians by the year 2020. Nearly half of that shortage is projected for primary care doctors (family physicians, pediatricians, and family practitioners). The federal Affordable Care Act (ACA) contains provisions to relieve the projected shortage of primary care professionals. Combined with the Prevention and Public Health Fund and the American Recovery and Reinvestment Act, the ACA will provide for the training, development and placement of more than 16,000 primary care providers, including physicians, over the next five years.

A significant deterrent to becoming a physician is the substantial cost of medical education. At an estimate cost of \$80,000 per year, a medical student can easily accrue a debt of up to \$400,000 upon graduation.

In an effort to reduce the nationwide shortage of primary care doctors, as well as lessen burdens on medical students, there is a movement toward an accelerated 3-year curriculum. This curriculum would allow medical students to receive the same amount of education in a concentrated, modified year-round education schedule, by eliminating the existing summer breaks, which occur currently in the standard four-year program. Reducing or eliminating the summer breaks allows for an accelerated curriculum completion date.

One such example is the Texas Tech University Health Sciences Center School of Medicine which offers a Family Medicine Accelerated Track (F-MAT) curriculum that provides 10-12 medical students the opportunity to obtain a medical degree in 3 years with 149 contact weeks, as opposed to a traditional 4-year program of 160 weeks. In addition, the F-MAT does not require the medical school student to pass USMLE Step 2CS prior to graduation, unlike most Liaison Committee on Medical Education (LCME) accredited medical schools. However, the F-MAT students will be required to pass USMLE Step 2CS during their first year of postgraduate training. Normally, LCME accredited medical school graduates are

required to pass USMLE Step 2CS as a graduation requirement and must pass USMLE Step 3 during residency training.

The F-MAT also has an incentive program where students are given a scholarship in their first year. It is estimated that approximately \$50,000 can be saved by the student in an accelerated 3-year program. This is a substantial economic incentive to a potential medical student.

The MBC additionally indicates that other medical schools are proposing competency-based tracks for students that excel and can progress at a faster rate than the standard 4-year program. Other programs may also be examining major clinical instruction in clinical settings outside of a traditional hospital setting.

It remains unknown how many weeks of clinical training in each of the core subjects and the total number clinical training weeks are required for graduation. Therefore, the MBC states that it is currently unable to determine if these accelerated programs meet the requirements of BPC §§ 2089–2091.2.

If it is determined that the accelerated programs do not meet the requirements of BPC §§ 2089 – 2091.2, legislative changes may be required in order to license graduates from the accelerated curriculum programs.

### Specifically:

- Section 2089(a) provides "a medical curriculum extending over a period of at least four academic years, or 32 months of actual instruction . . . the total number of hours of all courses shall consist of a minimum of 4,000 hours. At least 80% of actual attendance shall be required."
- Section 2089.5(b) provides "instruction in the clinical courses shall total a minimum of <u>72</u> weeks in length."
- Section 2089.5(c) provides "instruction in the core clinical courses of surgery, medicine, family medicine, pediatrics, obstetrics and gynecology, and psychiatry shall total a minimum of 40 weeks in length, with a minimum of eight weeks in pediatrics, six weeks in obstetrics and gynecology, a minimum of four weeks in family medicine and four weeks in psychiatry."
- Section 2089.5(d) provides "of the instruction . . . <u>54</u> weeks shall be performed in a hospital that sponsors the instruction . . ."

With the immediate need for a significant increase in the number of primary care physicians, in addition to the driving force of accessible and affordable medical care that resulted in the ACA, it may be prudent to conduct a review of these provisions of law to determine if increased Board discretion and flexibility is needed so that an LCME-accredited accelerated medical degree curriculum could satisfy the qualifications for licensure. These professional education programs would presumably boost primary care availability, and potentially increase medical care availability in the underserved areas of California, such as remote and rural communities.

The MBC points out that in addition to the expedited degree process, the practice of medicine has evolved such that the majority of clinical practice is no longer hospital based. The teaching of medicine must likewise be allowed to evolve with the practice.

The MBC recommends a review of the statutes to determine if increased flexibility is needed. If it is determined that a change is required, a provision to accommodate an accelerated medical degree program and other variations of clinical instruction outside of a hospital by an LCME accredited institution must be added.

Staff Recommendation: The MBC should commence, in cooperation with the appropriate stakeholders, a review of the applicable provisions of California law to determine if increased flexibility is needed in order to authorize LCME-accredited accelerated medical degree curriculum to meet the requirements for licensure in California. If it is determined that a legislative change is required, the MBC should submit to the Committee the appropriate amendment language.

### MBC Response (April 2013):

The issue of potential accelerated 3-year and competency-based medical school programs is one that the MBC is aware of occurring in other states. Although these programs do not yet exist in California, the MBC does want to learn more by working with interested parties, as graduates of these programs may come to the MBC for licensure and California may have programs similar to these in the future. The MBC needs to be proactive on this in order to ensure there are no obstacles to licensure. Per Senate B&P Committee staff's recommendation, the MBC will work with the appropriate stakeholders to review applicable provisions of existing law to determine if increased flexibility is needed. If the MBC does determine that a legislative change is required, the MBC will work with the Committee staff and submit appropriate language.

<u>ISSUE #4</u>: There should be consistency in the amount of time a physician and surgeon may be out of practice without receiving additional clinical training before renewing their license and/or allowing them to continue practice.

<u>Background</u>: The MBC has raised the following as a new issue in its Sunset Report. BPC § 2229 mandates that protection of the public shall be the highest priority for the MBC, and that whenever possible disciplinary actions shall be calculated to aid in the rehabilitation of licensees.

In addition, the MBC's Disciplinary Guidelines provide that, in the event a licensee experiences a period of non-practice of more than 18 months while on probation, the licensee shall successfully complete a clinical training program prior to resuming the practice of medicine. This short timeframe (18 months) has been adopted because the licensee already is on probation, and an 18-month period of non-practice has been identified as the reasonable cut off point before a clinical training program is required.

However, for a physician who has let his or her license expire, BPC § 2456.3 states, in part, "a license which has expired may be renewed at any time within 5 years after its expiration." In order to renew the license, the physician must simply submit the renewal paperwork, CME verifications, and pay the fees and penalties. Hypothetically, the license can be returned to

active status even if the physician has not practiced medicine for up to five or more years. For example, a physician who, during the last two renewal cycles, did not practice clinical medicine, and then allowed the license to lapse four years prior to renewing, could go back into some sort of clinical practice. The physician has not practiced for eight years, but can renew, pay fees, demonstrate that CME has been obtained, and go back into practice. Although the Board is not aware that this hypothetical ever has happened, it is a potential scenario that Board could face.

The Board recommends that legislation be considered to bring some consistency in the time that a physician may be out of practice before he/she has to show competency. If it is believed that five years is too long, then there may need to be a legislative change, but this is an issue worthy of study so it may be addressed. The study must include the availability of training programs to address re-entry training needs.

Staff Recommendation: The MBC should study the issue of whether allowing a physician to return to practice after a lapse in licensure or of practice of more than 18 months without completing additional training provides adequate public protection. The MBC should make recommendations to the Committee on its findings.

### MBC Response (April 2013):

The MBC would like to see consistency in the amount of time a physician may be out of practice. The MBC believes this issue should be further researched and studied, specifically if 18 months out of practice without additional training is an appropriate standard to use. The Federation of State Medical Boards has issued a paper on this matter and the MBC will work with it to research this matter and determine the appropriate action to take. Per Senate B&P Committee staff's recommendation, the MBC will study this issue and make recommendations to the Committee on its findings.

## <u>ISSUE #5</u>: Should there be a mandatory requirement for licensees to submit their Email address to the MBC, if they possess one?

<u>Background</u>: The MBC has raised the following as a new issue in its Sunset Report. The MBC believes it would be beneficial to require all licensees to provide the Board with an email address, if they possess one. Currently, providing an email address to the MBC is optional for applicants and licensees. An email address is requested on the application and renewal forms. When an email address is provided, it is considered confidential. When appropriate, the MBC sends some correspondence electronically instead of mailing to the physical address on record. This practice has proven to be a quicker, more convenient, and potentially more reliable delivery method while saving printing and postage costs. For example, the Board's Summer 2012 Newsletter was sent electronically via email to approximately 113,800 licensees and 6,800 applicants. In addition, when there is a FDA alert, it can be relayed in the same day the alert is released.

On rare occasions, licensee email addresses are used to send notices of important law changes, emergency regulations, as well as other urgent issues affecting licensees and public health. The MBC states that in such cases Executive and MBC staff review and approve these rare, relatively infrequent emails that are distributed.

The Board regularly posts information on its Internet Website to alert licensees of urgent issues. The Board also uses a subscriber list service to notify individuals about items of interest relating to the activities of the Board via email. Subscribers may choose to receive email alerts for some or all of the offered topics. This is a valuable tool to get important information to licensees and other interested parties, but it is not widely used by licensees. As of August 2012, there were less than 4,000 subscribers for each topic.

In addition, the MBC is moving to a new information technology (IT) system that will allow licensees to receive renewal notifications and other information via email. The new IT system will allow licensees the opportunity to choose the best method (i.e. electronically or U.S. Postal Service) of receiving information from the Board. SB 1575 Price (Chapter 799, Statutes of 2012) amended BPC § 2424 to allow the MBC to send email notifications for expired licenses. The Board wants to communicate with its licensees to provide the most current, meaningful, and important information in a 21st century manner, that is also respectful of the time that is taken going through email messages.

The MBC recommends a legislative change to require that licensees provide the Board with an email address, if they possess one. In addition, the language should state the email address provided will be confidential.

While Committee staff strongly agrees with the idea of using email addresses to communicate with licensees, staff questions the ultimate effectiveness of the proposed mandate. Since the MBC already requests email addresses on license renewal forms, and the proposed mandate is to require licensees to submit an email address, if they possess one. It leaves the possibility open of a licensee refusing or failing to submit an email address. Furthermore, since the proposal to make it a requirement, licensees and violation of the law could be subject to disciplinary action unprofessional conduct under BPC § 2234 (a).

<u>Staff Recommendation</u>: The MBC should address the concerns of Committee staff stated above, and submit to the Committee appropriate amendment language regarding licensees providing email addresses to the Board, if they possess one. The language should additionally require the MBC to keep a provided email address confidential.

### MBC Response (April 2013):

The MBC agrees with the Senate B&P Committee staff's concern on the effectiveness of this proposal. Committee staff is correct that including the requirement for email addresses, but only if a licensee possesses an email address, leaves the possibility open of a licensee refusing or failing to submit an email address. In response to this concern, the MBC has submitted language on March 5, 2013 to Committee staff that would require all licensees to provide the MBC with an email address. The language also makes it clear that any email address provided to the MBC is confidential and not subject to public disclosure.

<u>ISSUE #6</u>: Should the MBC continue to provide to the public information regarding a physician and surgeon's postgraduate training?

**<u>Background</u>**: The MBC has raised the following as a new issue in its Sunset Report. BPC § 803.1 states the Board shall disclose a physician's approved postgraduate training; § 2027

further requires the MBC Website to contain everything required to be disclosed in section 803.1. The Board currently collects limited postgraduate training information, and will disclose it upon request, but only posts the number of years completed in postgraduate training. This information is based upon information self-certified by the physician. The names of all the postgraduate training taken are not easily obtained for posting, thus it is not disclosed on the Website.

The MBC states that this information is submitted by applicants for a physician license during the time in which most applicants are in the first or second year of postgraduate training. The Board only collects the postgraduate information at the time of licensure. Any additional training they receive is not collected by the Board.

Additionally, the Board does not currently request additional postgraduate training information that the applicant may have received. If the Board were to begin to require it, the Board might then be required to verify this additional information. The collection of this information and the posting would be a huge and costly task.

The Board is unsure of the added value to consumer protection with the addition of specific postgraduate training program information on a physician's profile. To most members of the public, postgraduate training information is not the important information to use to determine if this is the correct physician for the patient. What is important to the public is whether the individual is board certified and what the practice specialty is for the physician. This is the information most members of the public want to know and find valuable. This information is not required but most physicians do provide it on their survey.

The Board recommends that the law should be amended to eliminate the requirements for the Board to post a physician's approved postgraduate training.

Committee staff is cautious about reducing board disclosures about licensees. Such information is generally believed to be valuable for consumers to make informed choices about the licensed professionals that they deal with. However, the MBC has indicated that the information required to be posted may very well be outdated and irrelevant to the licensee's practice, and thus fall short of giving consumers sound choices based upon valid information.

<u>Staff Recommendation</u>: The MBC should further discuss this proposal with stakeholders, including those stakeholders representing consumer interests and advise the Committee of the results of those discussions, and if appropriate the MBC should submit to the Committee amendment language to eliminate the requirement for the MBC to post a physician's approved postgraduate training.

### MBC Response (April 2013):

Existing law requires the Board to post information on physicians' approved postgraduate training. The MBC only collects limited postgraduate training information, thus it is not disclosed on the MBC's Web site. Currently, the MBC only posts the number of years completed in postgraduate training, and this information is self-certified by the physician. The MBC is not convinced that postgraduate training program information is valuable for consumers or that this information helps consumers make informed choices. Senate B&P

Committee staff has recommended that the MBC further discuss this proposal with stakeholders, including stakeholders representing consumer interests. The MBC will hold an interested parties meeting on this issue to have these discussions and update the Committee on the results. If the discussions support this disclosure requirement being eliminated, the MBC will submit language to Committee staff.

ISSUE #7: Clarify that the employment of physicians and surgeons in Accredited Residency Training Programs and/or Fellowship Programs does not violate the prohibition against the Corporate Practice of Medicine.

<u>Background</u>: The MBC has raised the following as a new issue in its Sunset Report. A question has been raised regarding whether the employment of residents is a violation of the prohibition against the corporate practice of medicine.

BPC § 2052, provides in part:

Any person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing . . . [medicine] without having at the time of so doing a valid, unrevoked, or unsuspended certificate . . . is guilty of a public offense.

BPC § 2400 provides in pertinent part:

"Corporations and other artificial entities shall have no professional rights, privileges, or powers."

The policy in BPC § 2400 against the corporate practice of medicine is intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment. The MBC has a long standing interpretation that physicians in an ACGME accredited postgraduate training (accredited residency) and/or fellowships do not meet the criteria for the prohibition against the corporate practice of medicine for several reasons, including:

- u.S. and Canadian medical school graduates training in California may practice medicine in an accredited residency program for up to 2 years before requiring a license to continue in the residency program. (BPC § 2065)
- b. International medical school graduates training in California may practice medicine in an accredited residency program for up to 3 years. (BPC § 2066)
- c. Residents do not practice medicine independently, since residents work under the supervision of a residency program director and other teaching faculty.

The MBC believes that the corporate practice of medicine issue regarding accredited residency programs and their residents should be clarified. The MBC has determined that the corporate practice of medicine as it relates to accredited residency and fellowship programs should be addressed as a specific exemption. The MBC states that there is clearly an emerging need to remove any possible misinterpretations regarding the corporate practice of medicine for accredited residency programs. This will ensure California accredited

residency/fellowship programs are not in danger of closing due to the concerns regarding the prohibition of the corporate practice of medicine.

The Board recommends that legislation be introduced to clarify that residents in California accredited resident/fellowship programs are exempt from corporate practice laws related to how they are paid.

<u>Staff Recommendation</u>: Committee staff agrees that the corporate practice of medicine issue regarding accredited residency programs and their residents should be clarified. The MBC should submit to the Committee specific language to clarify that participation in an accredited physician residency training program is not a violation of the prohibition against the corporate practice of medicine.

### MBC Response (April 2013):

In response to questions raised by interested parties, the MBC would like to clarify in statute that the employment of residents in accredited/approved residency programs is not a violation of the prohibition against the Corporate Practice of Medicine. The MBC submitted language on March 5, 2013 to Senate B&P Committee staff to clarify this issue.

## <u>ISSUE #8</u>: Should the requirement for the MBC to approve non-American Board of Medical Specialties be eliminated?

**Background:** The MBC has raised the following as a new issue in its Sunset Report:

**The Law and History.** In 1990, SB 2036 (McCorquodale), sponsored by the California Society of Plastic Surgeons, among others, sought to prohibit physicians from advertising board certification by boards that were not member boards of the American Board of Medical Specialties (ABMS). It added BPC § 651(h) to prohibit physicians from advertising they are "board certified" or "board eligible" unless they are certified by any of the following:

- An ABMS approved specialty board.
- A board that has specialty training that is approved by the Accreditation Council for Graduate Medical Education (ACGME).
- A board that has met requirements equivalent to ABMS and has been approved by the MBC.

The ultimate effect is to provide that unless physicians are certified by a board, as defined by law, physicians are prohibited from using the term "board certified" or "board eligible" in their advertisements. The law does not, however, prohibit the advertising of specialization, regardless of board certification status.

To implement BPC § 651, the MBC adopted regulations which are substantially based on the requirements of ABMS, including number of diplomates certified, testing, specialty and subspecialty definitions, bylaws, governing and review bodies, etc. The most notable requirement relates to the training provided to those certified by the specialty boards. In the regulations, training must be equivalent to an ACGME postgraduate specialty training program in "scope, content, and duration."

Since the regulations were adopted, the MBC has reviewed a number of specialty board applications, and has approved four boards:

- American Board of Facial Plastic & Reconstructive Surgery
- American Board of Pain Medicine
- American Board of Sleep Medicine
- American Board of Spine Surgery.

The MBC has also disapproved two boards:

- American Academy of Pain Management
- American Board of Cosmetic Surgery.

**Consumer Protection Function.** The purpose of the law and regulation is to provide protection to consumers from misleading advertising. Board certification is a major accomplishment for physicians, and while board certification does not ensure exemplary medical care, it does guarantee that physicians were formally trained and tested in a specialty, and, with the ABMS' Maintenance of Certification (MOC) requirements to remain board-certified, offers assurances that ongoing training, quality improvement, and assessment is occurring.

At the time the legislation was promoted, a number of television news programs covered stories from severely injured patients that were victims of malpractice from physicians who advertised they were board certified, when, in fact, they had no formal training in the specialty advertised. The law put an end to physicians' ability to legally advertise board certification if the certifying agency was not a member board of ABMS.

Is the Program Still Relevant? As explained, the law merely addresses advertising, and does not in any way require physicians to be board certified or formally trained to practice in a specialty or in the specialty of which they practice. Physicians only need to possess a valid physician's license to practice in any specialty. As prospective patients usually are covered by insurance, searching for a physician in most specialties is generally done through their insurance directory. At present, insurance companies generally only choose board-certified physicians for their panels, or those physicians whose credentials they have vetted.

The same is generally true for the granting of hospital privileges. Hospitals grant privileges after conducting a review of qualifications. This process, called "credentialing" will include looking into the background of a physician, including accredited training and board certification. For that reason, most physicians who are granted privileges will be board-certified in the specialty for which they are granted privileges, or similarly highly, formally trained.

Therefore, the "board certification" advertising prohibition is primarily meaningful for elective procedures; that is to say, those procedures that are not reimbursed by insurance or those performed outside of hospitals or hospital clinic settings.

**Cost of Program.** The cost for the MBC to administer the program has been minimal in recent years, since there has only been one recent application. It is likely that non-ABMS

certifying boards have been deterred from filing applications due to the law, the strict regulations, the demanding review process, and the fee.

Processing the application for meeting the basic requirements can be done by an analyst. The evaluation of the medical training, however, must be performed by a physician consultant that is an expert with academic experience. Generally the consultant used is an emeritus professor of medicine and former training program director who has served on residency review committees. (Residency review committees are part of the ACGME/ABMS review process.)

Therefore, a medical education expert must be hired to perform a review of the specialty board's formal training program. The cost of the expert varies, but when the fee regulations were promulgated in the 1990s, it was estimated that such a review would require from 80 to 160 hours to complete. At present, the cost of hiring an expert would be from \$5,000 to \$11,000.

The current application fee for a specialty board application is \$4,030. (The fee was determined not by hours, however, but by the average costs of all three boards at the time they had been reviewed.) By law, however, the Board has the authority to raise the fee to cover reasonable costs associated with processing the application.

Ultimately, the costs of processing specialty board applications has not been the major expense in this program. The cost comes when an application is denied, and litigation results, and thereby legal costs.

**Risk of Lawsuits and Potential Payouts.** Since the program's inception, the MBC has only denied two specialty boards. American Academy of Pain Management was denied, and filed four suits against the MBC, including one in Federal Court. American Board of Cosmetic Surgery applied for approval twice, was denied both times, and filed suit on the second denial.

The MBC states that it has prevailed in all litigation, but the cost has been considerable. While AG billing methods makes it difficult to ascertain the exact cost of legal representation specific to the suits, MBC estimates its litigation costs conservatively to be in excess of \$200,000.

*Use of Medical Consultants and Experts.* When the original legislation was introduced in 1990, the MBC opposed the bill because it could see tremendous problems in implementation. The ABMS is a well-established, huge organization with tremendous resources, both in revenue, infrastructure, and expertise, far beyond the MBC's resources.

The law asks the MBC to essentially perform most of the same tasks as the ABMS, the ACGME, and the specialty boards and their residency review committees – with a fraction of their resources. In contrast, the MBC must use academic medical training experts to conduct reviews and provide recommendations to the MBC. Unlike the ABMS process, the MBC is not a part of developing the curriculum or training programs, but is being required to consider whether or not the criteria for certification and the training provided is "equivalent" as defined by the regulation.

Other than the Board, Who Could Fulfill this Function? According to the MBC, three entities have the expertise to review and evaluate the quality of medical specialty boards' training and certification criteria: (1) ABMS, (2) ACGME, and to a lesser degree (3) medical schools that provide ABMS designed and ACGME accredited residency training programs. Unfortunately, according to the MBC, it would be inappropriate for any of these entities to judge a competing specialty board training program.

**Factors to Consider.** To determine whether or not this program's benefits outweigh its cost, the MBC recommends consideration of the following:

- 1. The existing law is designed to prevent consumers from being misled by physician advertising to deter physicians from advertising board certification. In that sense, the law has provided such a deterrent, and the MBC has the legal authority to combat this practice.
- 2. Physicians are not prohibited from advertising that they specialize in procedures for which they have little training or qualifications, and may advertise that they are members or "diplomates" of various boards that are not ABMS or the equivalent. The current law only relates to advertising, and does nothing to prevent physicians from practicing in specialties for which they are not certified.
- 3. The cost of processing applications has been minimal; however, the cost of litigation has been substantial. Should more specialty boards apply and be disapproved, it is likely that there will be future legal costs.

The Board recommends that the Legislature delete the provision requiring the MBC to approve non-ABMS specialty boards. For consumer protection, the law should continue to require physicians to advertise as board certified only if they have been certified by ABMS boards and the four additional boards currently approved by the MBC. In addition, the law could be amended to prevent the use of other misleading terms.

Staff Recommendation: The MBC should submit a specific legislative proposal to the Committee to delete the provision requiring the MBC to approve non-ABMS specialty boards, and to prevent the use of other misleading terms. Consideration should be given to amending BPC § 651(h) to delete the MBC's authority to approve non-ABMS specialty boards, and to prevent the use of other misleading terms in physician and surgeon advertising, as recommended by the MBC.

### MBC Response (April 2013):

The MBC is recommending that the statute be amended to require physicians to advertise as board certified only if they have been certified by ABMS boards and the four additional boards currently approved by the MBC. The MBC submitted language on March 5, 2013 to Senate B&P Committee staff to amend the statutes in this regard.

## **ENFORCEMENT ISSUES**

**Background:** In November and December of 2012, the *Los Angeles Times* published a series of four articles which were the outcome of an intensive review of the epidemic of prescription drug-related deaths in four Southern California counties. In the investigation, reporters examined coroners' records and interviewed doctors, regulators, law enforcement officials and relatives of those who died from overdoses. The investigators also created and analyzed a searchable database of 3,700 drug related deaths during a 5-year span (2005-2011) in Southern California to identify those tied to doctors' prescriptions.

An examination of coroner records by the *Times* found that:

- In 47% of those cases (1,762 deaths) drugs for which the deceased had a prescription were the sole cause or a contributing cause of death.
- A small number of doctors were associated with a disproportionate number of those fatal overdoses. 0.1% of the practicing physicians (71 physicians) in the 4 counties wrote prescriptions for drugs that caused or contributed to 298 deaths. That is 17% of the total deaths linked to doctors' prescriptions.
- Each of the 71 physicians prescribed drugs to 3 or more patients who died.
- 4 of the physicians had 10 or more patients who fatally overdosed.
- One physician had 16 patients who died.

The *Times* found that the 71 physicians with 3 or more fatal overdoses among their patients are primarily pain specialists, general practitioners and psychiatrists. Four of the physicians have been convicted of drug offenses in connection with their prescriptions, and a fifth is awaiting trial on second-degree murder charges in the overdose deaths of 3 patients. The remaining physicians have clean records with the MBC, according to the *Times*.

[Note these numbers: in FY 00/2001 the MBC initiated 2,320 investigations, and in FY 11/12, 1,577 investigations were opened - a decrease of 42%.]

The Board's Enforcement Program has faced significant challenges in the last four years that have impacted the Program's performance.

Average times from complaint intake to the completion of the investigation have also increased. In the Board's 2002 Report, in FY 00/01 it took 257 days on the average, and in FY 11/12 it took  $347 - \underline{\text{an increase of } 74\%}$ .

The *Times* articles further stated that there are about 30 fewer investigators today than in 2001.

Historical background. Because of skyrocketing medical malpractice insurance costs, in 1975, AB 1 (Keene) enacted the Medical Injury Compensation Reform Act of 1975 (MICRA), a measure carefully designed to comprehensively address three issues — tort reform, medical quality control, and insurance regulation — that were of interest to the 4 sets of stakeholders "at the table" (physicians, lawyers, insurance companies, and patients).

MICRA created the cap of \$250,000 for punitive damages in malpractice suits, a cap that remains to this day and is unique to civil actions brought against professional licensees. In addition, attorney contingency fees were also limited.

As a trade-off in order to reach such a sweeping agreement, however, the medical profession had to make concessions too. The concession made was a new, improved, better equipped, less physician oriented and more publicly minded Medical Board. In addition, the Board would have its own enforcement team, trained peace officers that would investigate complaints against doctors. Part of the Act required mandatory reporting to the Board of hospital discipline and malpractice awards.

The rationale of this compromise was simple. Punitive damages do not remedy injury. Prevention of malpractice that could occur, due to a more efficient Medical Board, would save lives and injury, and, after much debate, the bill was passed and a new Board was born.

The reforms of MICRA were balanced partially on the creation of a regulatory board which would engage in vigorous enforcement of the law against bad doctors in order to protect the safety of consumers.

In 2005, SB 231 (Figueroa) made a number of changes recommended by the MBC's Enforcement Monitor. Among those changes was the establishment of a Vertical Enforcement (VE) pilot program. Under VE, prosecutors from the Attorney General's (AG) Health Quality Enforcement Section (HQES) are paired with MBC investigators from the initial assignment of the case for investigation all the way through the final prosecution of the case. The idea is to bring about better cases and better outcomes for the safety of patients.

As initially drafted, the VE program in SB 231 in 2005 would have transferred the MBC's investigators to the HQES in the AG's office. This would have placed the investigator and prosecutor in the same office under the same agency, a practice, as is done in numerous other law enforcement shops throughout the country. Ultimately the transfer of investigators was taken out of the bill, but the idea of paring prosecutors and investigators from start to finish on a case remained.

Even though progress has been made in improving investigations and prosecution of disciplinary cases involving physicians and surgeons under VE over the last 6 years, there still is a long way to go to ensure the public is well protected.

<u>Staff Recommendation</u>: The VE program should be continued, and additional improvements should be identified which would further enhance the collaborative efforts of the MBC investigators and HQE prosecutors.

### MBC Response (April 2013):

In 2005, SB 231 established the Vertical Enforcement (VE) pilot program. Under VE, MBC investigators are paired with prosecutors from the Attorney Generals' Health Quality Enforcement Section (HQES) from the initial assignment of cases for investigation, all the way through the final prosecution of the case. The MBC believes this model is working and does not think that the Legislature should revisit the original proposal to move MBC investigators to the Department of Justice. The MBC submitted a supplemental report to the Senate B&P Committee on Monday, March 4th, which included a review of pertinent data for the VE program. The MBC believes that the benefits of VE are significant and does not believe that any legislative amendments to the program need to be made at this time. The

MBC recognizes there have been challenges in the implementation of VE, but those challenges can be overcome through continued collaboration between the MBC and HQES, and revisions to the procedural manuals used by both staffs. Here are some areas that the MBC is committed to working on in a collaborative manner with HQES:

- The MBC will be working with HQES to establish best practices and identify other areas where improvements can be made. As issues arise, the MBC will meet with HQES to resolve any issues and will formalize the resolution in the VE Manual. In addition to the quarterly supervisor meetings, quarterly meetings with MBC and HQES management, a Subcommittee of the MBC has been established in order to determine what progress has been made and what amendments or enhancements need to be made to the VE model and Manual.
- In order to reduce the DAG's workload so they may reallocate resources to high
  priority items, the MBC is recommending that criminal conviction cases that do not
  involve quality of care, should not require DAG involvement until the matter is ready
  for the filing of an Accusation. This will enable the DAGs to focus on high priority
  matters, such as interim suspension orders, enforcement subpoenas, preparing the
  expert reviewers for hearing, etc.
- Interim suspension orders are essential to consumer protection. These orders remove a physician who has a potential to endanger the public from practicing medicine. With the DAGs being involved earlier in the case, this allows them to know the case and be able to prepare the necessary documents to petition the court for the suspension. This results in obtaining the suspension order in a more expeditious manner. The MBC plans on continuing to focus on these cases with management of HQES, which will result in better consumer protection.
- Subpoena enforcement actions for obtaining medical records and a physician interview are critical as the MBC is unable to determine whether the physician's actions are egregious until the medical records have been obtained and reviewed and the physician interviewed. The MBC adopted a "zero tolerance" policy in 2009 for delays in medical record acquisition and the physician interview. The DAG's attention to the process of subpoena enforcement is essential and eliminating the DAGs time on criminal conviction cases will assist in a reduction in the time to process these subpoenas.
- The MBC through its Expert Reviewer Training Program has determined that the
  experts need more communication and preparation with the DAGs. It is
  recommended that the DAG have the expert review the Accusation prior to filing and
  meet with the expert prior to the hearing to review the case and prepare for testifying.
  This will prepare the expert for the hearing and ensure the expert understands the
  hearing process.

The MBC realizes the importance of the VE model and will continue to strive towards its improvement with the overall goal of meeting the MBC's mandate of consumer protection. The MBC looks forward to working with the Senate B&P Committee, the Attorney General's (AG's) Office, and interested parties, to identify improvements that would further enhance collaborative efforts of both the MBC and the AG's Office.

<u>ISSUE #10</u>: (JURISDICTION OVER UTILIZATION REVIEW DECISIONS.) Should the Medical Board investigate complaints that relate to utilization review decisions in the

### workers' compensation system regarding physicians and surgeons who may have

<u>Background</u>: The MBC has for many years publicly asserted that when a medical director of a health plan or a utilization review physician in the workers' compensation system uses medical judgment to delay, deny or modify treatment for an enrollee or injured worker, that act constitutes the practice of medicine. This position, expressly stated on the MBC's website, has been presumed to be a correct interpretation of the Medical Practice Act by Legislators, regulators, physicians, and others involved with the Board. If a decision which is contrary to the standard of care leads directly to patient harm, the MBC should have clear authority to investigate the matter to determine whether the physician has engaged in unprofessional conduct.

In the workers' compensation system, an insurer or self-insured employer is entitled to retain a physician to conduct "utilization review" of treatment recommendations made by the injured worker's physician. This decision can have the effect of determining what treatment the injured worker will receive. The utilization review physician is supposed to exercise his or her independent medical judgment. However, concerns have been expressed by treating physicians that insurer or self-insured employer rules that violate the standard of care are being enforced by utilization review physicians. If this were the case, and a patient is harmed, it has been assumed that the utilization review physician's decision would be subject to MBC oversight. Recent actions and statements by the MBC staff contradict this assumption.

Complaints alleging that utilization review decisions made by California-licensed physicians that: (1) violate the standard of care, and (2) cause significant harm, have been rejected by MBC staff as being outside the Board's jurisdiction. Certainly, the MBC does not have the authority to direct an insurer to pay for treatment – that is within the authority of the Division of Workers' Compensation, but the existence of an administrative remedy for the harmed patient is no more a barrier to MBC jurisdiction over the physician than a medical malpractice award is to a patient harmed by standard of care violations in the group health care market.

<u>Staff Recommendation</u>: The MBC should have jurisdiction over medical decisions made by California-licensed physicians and surgeons who conduct utilization reviews. The MBC should also report to the Committee on its plan to direct enforcement staff to implement enforcement oversight over these decisions. The MBC should also make the worker' compensation system aware of this requirement.

### MBC Response (April 2013):

The issue of the MBC's authority regarding workers compensation utilization review decisions, has recently been brought to the MBC's attention. This issue was brought up at the MBC's January 31, 2013 Enforcement Committee meeting in particular, and then again at the Full Board Meeting on February 1, 2013. The Enforcement Committee has asked for a full discussion regarding this issue. Therefore, this item will be on the agenda for the next Enforcement Committee meeting on April 25, 2013 in Los Angeles. Board staff will keep the Senate B&P Committee informed of the discussion at the Enforcement Committee Meeting and any action taken by the Full Board, including decisions on enforcement oversight and any necessary notification to the worker's compensation system.

# <u>ISSUE #11</u>: (PUBLIC DISCLOSURE PRACTICES OF THE MBC.) To what extent have the recommendations made by the California Research Bureau regarding public disclosure been implemented?

Background: SB 231 (Figueroa, Chapter 674, Statutes of 2005) required the Little Hoover Commission to conduct a study and make recommendations on the role of public disclosure in the public protection mandate of the MBC. SB 1438 (Figueroa, Chapter 223, Statutes of 2006) then transferred the responsibility to conduct the study to the California Research Bureau (CRB) of the California State Library. The study titled *Physician Misconduct and Public Disclosure Practices at the Medical Board of California* was completed November 2008 and offered 11 policy options for improving public access to information about physician misconduct.

Although some options required legislation to implement a couple of the recommendations, most could be implemented by the MBC without legislation. For example, the MBC expanded the physician profile on its license lookup Website to include items from the physician survey including board certification. In addition, the MBC adopted a regulation in 2010 that requires a physician inform consumers where to go for information or where to file a complaint about California physicians.

However, it is unclear to what extent that the other recommendations in the CRB Report have been implemented. Are there additional policy or regulatory changes that could be made by the MBC to implement the recommendations? Are there statutory changes that should be made to implement recommendations in the report?

<u>Staff Recommendation</u>: The MBC should inform the Committee to what extent the 11 policy options recommendations made by the California Research Bureau have been implemented? In its response, the MBC should identify and recommend to the Committee whether additional MBC policies or regulations should be changed and whether additional legislation should be enacted to implement the recommendations made by the CRB.

### MBC Response (April 2013):

The California Research Bureau (CRB) conducted a study titled "Physician Misconduct and Public Disclosure Practices" in 2008, which offered 11 policy options for improving public access to information about physician misconduct. These options focused on improving public disclosure and access. Since this report, the MBC has made significant changes to ensure transparency and expedite public notice regarding MBC actions. The MBC adopted a regulation (effective June 27, 2010), which requires all physicians in California to inform their patients that they are licensed by the Medical Board of California, and to include the MBC 's contact information. This information can be posted in the physician's office or given to the patient in writing. The MBC has developed a subscriber's list that allows any individual to go to the MBC's Web site and sign up to receive regular information feeds from the MBC via an email alert, including disciplinary action taken against a physician, new proposed regulations, the release of the MBC's Newsletter, or notification of an upcoming meeting. The MBC also now posts all MBC agendas and meeting materials online, allowing the public to review the entire MBC packet, prior to the MBC meetings. The MBC has begun Webcasting its

meetings when possible, and those Webcasts remain available for viewing on the MBC's Web site.

The MBC also revamped and improved the look-up function on its Web site public disclosure screen. Members of the public can now verify that a physician's license is renewed and current, see any disciplinary action (or other actions, such as a conviction, malpractice judgment award, other state discipline, etc.), view the information physicians have provided in their physician survey (such as ethnicity, foreign language spoken, board certification, etc.), and view any disciplinary documents based upon the MBC's action.

The following indicates the policy options from the CRB and how the MBC has implemented the recommendation or the reason for not implementing the recommendation. The MBC believes that legislation should be sought based upon one item (#2) of the CRB report. The method of receiving information regarding a physician should be consistent no matter the method of request (CRB Policy Option 2). The MBC requested, in its Sunset Review Report, a change in statute to eliminate the ten year requirement for public disclosure. MBC staff provided language on March 5, 2013 to the Senate B&P Committee for this legislative change (see Committee Issue 36 below).

**Policy Option 1:** Add a "public disclosure" component to the Medical Practice Act's list of the Medical Board of California's (MBC) responsibilities in Business and Professions Code Section 2004.

**MBC Action and Response:** Although public disclosure is not listed in section 2004, there are other sections in the Medical Practice Act that require public disclosure which the Board takes very seriously (Business and Professions Code section 803.1 and 2027). The MBC has worked diligently to post all items on a physician's profile allowed by law. The addition of this item into statute seems redundant.

**Policy Option 2:** Standardize the MBC's statutory disclosure requirements across different outlets (e.g., Internet vs. in-person or in-writing requests), including requiring permanent disclosure of past disciplinary actions, citation/fine actions, administrative actions, and malpractice judgments, arbitration awards and settlements.

**MBC Action and Response:** The study appropriately indicated the laws regarding disclosure and access to records are inconsistent, and should be amended. Any change in the length of time actions are posted on the Board's Web site requires a legislative change. The MBC raised this issue in its Sunset Review Report. The MBC requested that the limited ten year posting requirement for its Web site be removed. The MBC submitted language on March 5, 2013 to the Senate B&P Committee staff to make this amendment.

**Policy Option 3:** Direct the MBC to expand and revise its Internet physician profiles to better conform to current law, e.g. displaying specialty board certification and postgraduate training information.

**MBC Action and Response:** The MBC has implemented a new physician profile display that includes self-reported board certification, the number of years of postgraduate training and other information provided on the physician survey. The MBC plans to enhance the look up system for searches on partial or similar spelled names once the new BreEZe system is implemented and fully operational.

**Policy Option 4:** Direct the MBC to investigate and provide summaries of those investigations to the public for each reported malpractice judgment, arbitration award and settlement.

**MBC Action and Response:** This suggestion requires a legislative change and the MBC has not approved moving this forward as it is uncertain of the benefit of these types of summaries now that the public has easy access to the disciplinary record.

**Policy Option 5:** Direct the MBC to study ways to enhance public outreach in order to better identify cases of potential physician misconduct.

**MBC Action and Response:** The report suggested the MBC audit physicians' or hospitals' records. The Board does not have the ability to review patient records without a release or a reason to subpoena the records. Therefore, this would require a legislative change, additional funding, and staff. The MBC believes that studying its own data to identify possible educational opportunities may be more attainable. As requested by the MBC Board Members, the MBC staff has plans to begin the process of data review in early summer 2013.

**Policy Option 6:** Direct the MBC to require physicians to notify patients that complaints about care may be submitted to the Board.

**MBC Action and Response:** In 2010, California Code of Regulations section 1335.4 "Notice to Consumers" became effective to require physicians to post information in the office or inform patients in writing on how to contact the MBC. The notice requires the inclusion of the MBC's telephone number and Web site address.

**Policy Option 7:** Direct the MBC to expand information provided on its Internet physician profiles to include additional biographical data, including age, gender and training. **MBC Action and Response:** The Board's Web site was revised to include this information if the physician has agreed to post this information (with the exception of age). The Web site can display gender, ethnicity, and foreign language proficiency in addition to all the other information, including board certification, postgraduate training years, etc. However, because this information is not mandated, a physician may decline to disclose this information on his/her physician profile. To require posting, the data a legislative change would be necessary and could be very controversial due to the information the MBC is being requested to add, i.e. age and gender. Therefore, the MBC has taken the approach to post this information (except age) if approved by the physician.

**Policy Option 8:** Direct the MBC to provide on its Internet physician profiles links to evidence-based, physician-level performance information provided by external organizations, such as the California Physician Performance Initiative.

**MBC Action and Response:** To add the information to the MBC's physician profiles requires a legislative change. However, the MBC is not certain of the benefit of this information or the accuracy. The MBC believes at this time that there are many flaws in the quality and consistency of "physician level performance information" provided by external organizations, as these organizations measure different things. Until this work matures to the point that the information is valid, risk adjusted, and universally available for all licensees, it would be misleading to add this information to the Web site.

**Policy Option 9:** Direct the MBC to sponsor and publish research projects based on the contents of the Board's complaints, discipline, public disclosure and licensing databases.

**MBC Action and Response:** As staff time and funding permits, further research will be completed. The MBC's current Strategic Plan has a significant number of studies that MBC plans to conduct. The MBC is beginning to perform these studies and will be providing the information obtained on its Web site and in its Newsletter.

**Policy Option 10:** Direct the MBC and the California Board of Registered Nursing to develop methods for sharing and publicizing information about supervisory relationships between physicians and nurse practitioners.

**MBC Action and Response:** The report recommends tracking and posting the nurse practitioners and physician assistants who work under the physician's supervision. With the number of physicians in the state and the frequent changes that occur in employment, this may be an unmanageable task without any significant benefit. As complaints are received by each board, if there is a need to investigate the supervisor, the information is shared between boards for appropriate action.

**Policy Option 11:** Encourage the MBC to improve public access to and utility of MBC-provided information, such as establishing a web log ("blog") to provide notices of disciplinary actions now distributed via an email notification service to subscriber.

**MBC Action and Response:** The MBC currently emails disciplinary/administrative action notifications to any individual who requests to be on the MBC's Subscriber's list. The public documents are available on the MBC's Web site and the MBC's Newsletter maintains a list of disciplinary actions taken in the last quarter. In addition, the MBC currently has a Webmaster who responds to emails to the MBC. In addition, the MBC's Education Committee has begun a discussion exploring the potential role of social media as an avenue to expand public access to MBC information.

<u>ISSUE #12</u>: (SURGICAL CLINIC OVERSIGHT BY MBC.) Has MBC fully implemented all the provisions of SB 100? Are there functions that the MBC should continue to improve as it implements SB 100?

**Background:** SB 100 (Price, Chapter 645, Statutes of 2011) provided for greater oversight and regulation of surgical clinics, and other types of clinics such as fertility and outpatient settings, and to ensure that quality of care standards are in place at these clinics and checked by the appropriate credentialing agency. Accrediting agencies that accredit these outpatient settings are approved by the MBC. Specifically, SB 100 included the following provisions:

 <u>Laser or Intense Pulse Light Devices</u>. On or before January 1, 2013, the MBC shall adopt regulations regarding the appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures.

In 2010 the MBC established the Advisory Committee on Physician Responsibility in the Supervision of Affiliated Health Care Professionals (Advisory Committee) to determine the appropriate level of physician supervision at medical spa clinics. The Advisory Committee conducted several meetings on this issue; however, it is unclear whether recommendations were established and adopted. The MBC should update the Committee on the findings and recommendations of the Advisory Committee and

whether the MBC has adopted the regulations relating to physician availability at clinics or settings that use laser or intense pulse light devices.

2. <u>In vitro fertilization</u>. The MBC shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.

The MBC should inform the Committee how many outpatient settings that offer in vitro fertilization are currently accredited, and whether any new standards were adopted for outpatient settings that offer in vitro fertilization.

Additionally, the MBC should inform its licensees that settings that offer in vitro fertilization must be accredited.

Clinics outside the definition of outpatient settings. The MBC may adopt regulations it
deems necessary to specify procedures that should be performed in an accredited
outpatient setting for facilities or clinics that are outside the definition of outpatient
setting.

The MBC should inform the Committee whether it has adopted regulations for clinics that are outside the definition of outpatient settings. Additionally, the MBC should inform its licensees of any regulations that are adopted.

4. <u>Reporting Requirements</u>. An outpatient setting shall be subject to specified adverse reporting requirements and penalties for failure to report.

SB 100 subjected outpatient settings to the adverse event reporting requirements contained in Section 1279.1 of the Health and Safety Code. An outpatient setting must report to the Department of Public Health within 5 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. Adverse events include surgical events, product or device events, patient protection events, environmental events, criminal events, an adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor. Civil penalties in the amount not to exceed \$100 for each day that the adverse event is not reported may be assessed by DPH.

The MBC should inform the Committee whether it has established an arrangement or a memorandum of understanding with DPH to obtain information on outpatient settings with adverse reports. Additionally, the MBC should notify all outpatient settings of this requirement and inform accrediting agencies of its obligation to report to the DPH adverse events that are found during inspections.

5. <u>Information on the Internet Website</u>. The MBC shall obtain and maintain a list of accredited outpatient settings from the information provided by the accreditation agencies approved by the MBC, and shall notify the public by placing the information on its Internet Website, whether an outpatient setting is accredited or the setting's accreditation has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency. Specifies the information that must

be posted on the Internet Website.

Committee staff tried searching the MBC's list of outpatient settings and encountered several flaws. First, the Internet page for Outpatient Surgery Settings is not easy or intuitively found on the MBC Website. Second, after accessing the Outpatient Surgery Setting Database, Committee staff found that you have to scroll through page after page of listings in order to find the information on the particular surgery center you are looking for. A consumer cannot just plug in the name of the surgery center they are looking for to get the information. Ultimately, the database is presented in such a way that it appears that the relevant information would at best be difficult for consumers to find. The MBC should update the database lookup so that consumers may more easily find useful information on an outpatient setting.

Staff Recommendation: The MBC should update the Committee on its efforts to implement SB 100, including: (1) The findings and recommendations of the Advisory Committee and whether the Board has adopted regulations relating to physician availability at clinics or settings that use laser or intense pulse light devices; (2) How many outpatient settings that offer in vitro fertilization are currently accredited, and whether any new standards were adopted for outpatient settings that offer in vitro fertilization; (3) Whether the Board has adopted regulations for clinics that are outside the definition of outpatient settings; (4) Whether the Board has established an arrangement or a memorandum of understanding with DPH to obtain information on outpatient settings with adverse reports. The MBC should further do the following, and report back to the Committee: (1) Inform licensees and the public that settings that offer in vitro fertilization must be accredited. (2) Inform of any regulations for clinics that are outside the definition of outpatient settings that are adopted by the Board. (3) Notify all outpatient settings of the reporting requirement under Health and Safety Code § 1279.1 and inform accrediting agencies of its obligation to report adverse events that are found during inspections to the DPH. (4) Update the database lookup so that consumers may more easily find useful information on outpatient settings.

### MBC Response (April 2013):

SB 100 (Price, Chapter 645, Statues of 2011) required the MBC to adopt regulations on or before January 1, 2013, on the appropriate level of physician availability necessary within clinics or other settings using laser or intense pulse light devices for elective cosmetic surgery. The MBC held two interested parties meetings via the MBC's Physician Supervisory Responsibilities Committee. The first meeting was in April, 2012 in Long Beach, and the second meeting was held on July 20, 2012 in Sacramento. MBC staff received feedback at both of these meetings and drafted regulatory language based on discussions at these meetings.

The regulatory language is as follows: "Whenever an elective cosmetic procedure involving the use of a laser or intense pulse light device is performed by a licensed health care provider acting within the scope of his or her license, a physician with relevant training and expertise shall be immediately available to the provider. For the purposes of this section, "immediately available" means contactable by electronic or telephonic means without delay, interruptible, and able to furnish appropriate assistance and direction throughout the performance of the

procedure and to inform the patient of provisions for post procedure care. Such provisions shall be contained in the licensed health care provider's standardized procedures or protocols."

The public regulatory hearing was held on October 26, 2012, where the MBC adopted the above language. These adopted regulations were sent to Office of Administrative Law (OAL) on March 4, 2013 for its review and approval. If the regulation is approved by OAL, it will become effective in approximately 60 days or around May 4, 2013. The MBC also voted, in the interest of public protection, to recommend a statutory change to require that the regulations apply to all clinic settings (not only those using laser or intense pulse light devices for elective cosmetic surgery), and to require the MBC adopt regulations to establish the knowledge, training, and ability a physician must possess in order to supervise other health care providers. This need for legislation was provided in the MBC's Sunset Review Report. The MBC will submit to the Senate B&P Committee staff, upon submission of this report, language that can be considered for this enhancement.

SB 100 requires the MBC to adopt standards it deems necessary for outpatient settings that offer in vitro fertilization and allows the MBC to adopt regulations to specify procedures that should be performed in an accredited setting for facilities or clinics that are outside the definition of an outpatient setting. The MBC has not held public workshops on these, thus it has not yet adopted either regulation. The MBC had focused on adopting the availability regulations required by SB 100 and implementing other public disclosure elements of the bill prior to addressing these two regulatory elements. The MBC will consider the adoption of further regulations through public workshops in the summer/fall of 2013.

The MBC does not gather information on the types of outpatient settings, so it does not have data on the number of outpatient settings that offer in vitro fertilization. This is something the MBC may be able to collect in the future, especially if standards are adopted for this type of outpatient setting. The MBC will continue to research these issues and keep the Committee apprised of its progress and notified when public workshops will be held.

SB 100 requires outpatient settings to report adverse events under Health and Safety Code Section 1279.1 to the California Department of Public Health (CDPH). The MBC has met with CDPH several times on this issue. CDPH is working on a memorandum of understanding (MOU) so it can legally share these adverse event reports with the MBC. However, this MOU has not yet been finalized; as such, the MBC has not yet received any adverse event reports from CDPH. The MBC will continue to work with CDPH on this issue and keep the Committee apprised of its progress. MBC staff met with the four accrediting agencies to inform them of the requirements of SB 100, including adverse event reporting and asked them to notify their outpatient settings. The MBC will determine if the accrediting agencies notified the outpatient surgery settings and if not, then the MBC will notify the settings. The MBC has provided information on SB 100 and its requirements to all physicians, including those who work in outpatient settings, via its newsletter in January 2012.

Lastly, pursuant to SB 100, the MBC has created the Outpatient Surgery Setting Database, which can be accessed through the MBC's Web site. A consumer can search by owner name or setting name to access pertinent information intended to provide transparency and help consumers make informed decisions. The MBC agrees that this database is not the

most user friendly system at this time. However, the MBC has already made significant improvements to this database to make it more consumer friendly. The MBC will work with the accrediting agencies to ensure the required data continues to be received in a timely manner and posted on the Web site. In addition, in order to make the database easier for consumers to find, the MBC recently added a link to this database on its home page. This allows users to go directly from the MBC's home page to perform a search for an outpatient setting. The MBC will continue to make improvements as necessary to ensure consumers are informed.

The MBC has invited the four accreditation agencies to present at its next Board Meeting in April on the accreditation process, procedures, and requirements. This will allow the MBC to determine the communication between the accreditation agencies and the outpatient settings and ensure this is being conducted. The MBC will continue to update the Committee on the actions taken to implement SB 100.

### **ISSUE #13:** Implementation of peer review requirements pursuant to SB 700.

**Background:** In 2008 a study required by BPC § 805.2 was completed, which involved a comprehensive study of the peer review process. The study, performed by Lumetra, also included an evaluation of the continuing validity of BPC §§ 805 and 809 through 809.8 and their relevance to the conduct of peer review in California. The study found, among other things, that there were inconsistencies in the way entities conduct peer review, select and apply criteria, and interpret the law regarding BPC § 805 reporting and § 809 hearings. SB 820 (Negrete McLeod, 2009) sought to define the requirements and clarify the peer review process based on the results of the study; however the bill was vetoed. Subsequently, SB 700 (Negrete McLeod, Chapter 505, Statutes of 2010) was enacted, which focused on enhancements to the peer review system and made other improvements to peer review.

<u>Staff Recommendation</u>: The MBC should report to the Committee regarding the implementation of SB 700, and the extent to which it is receiving the reports required under SB 700.

### MBC Response (April 2013):

Pursuant to Business and Professions Code section 805, certain peer review bodies must report to the MBC actions pertaining to staff privileges, membership, or employment. In FY 2011/12, 114 reports were received pursuant to section 805, however, the MBC does not track the number of reports received pursuant to the individual subdivisions of section 805. The MBC has noticed a decline in the number of 805 reports received.

SB 700 (Negrete McLeod, Chapter 505, Statutes of 2010) added Section 805.01 to require the chief of staff of a medical or professional staff, a chief executive officer, medical director, or other administrator of a peer review body, to file a report following a formal investigation within 15 days after a peer review final determination that specified acts may have occurred, including gross negligence, substance abuse, and excessive prescribing of controlled substances. From January 1, 2011 (the first report received is dated April 1, 2011) to March 11, 2013 there were 25 reports received by the MBC pursuant to section 805.01. This bill also required the MBC to post a factsheet on the its Web site that explains and provides

information on 805 reporting, in order to help consumers understand the process and what 805 reporting means. The fact sheet was posted on the MBC's Web site on December 30, 2010.

The MBC not only notified the licensees of the new reporting under section 805.01 in its Newsletter, but has had several articles about 805 reporting in its Newsletter. The MBC also incorporates these reporting requirements into outreach provided to the groups who would be required to report.

There are multiple potential explanations to account for the observed decline in 805 reporting, including: hospitals finding problems earlier and sending physicians to remedial training prior to an event occurring that would require an 805 report; with the implementation of electronic health records and the mining of medical record data by the health entities, early identification is a real possibility; the growing use of hospitalists providing care to hospitalized patients, concentrating the care in the hands of physicians who specialize in inpatient care and who are less prone to errors than physicians who provide the care on only an occasional basis; etc. Or, the decline may be due to under- reporting. However, because the MBC does not have jurisdiction over the hospitals, it has no way of knowing the reason for the decline. CDPH and other hospital accrediting agencies have the authority to review hospital records and conduct inspections of the hospitals. For this reason, the MBC is recommending that existing law be amended to require state agencies and hospital accrediting agencies to send reportable peer review incidents found during an inspection of the facility to the MBC. The MBC has submitted language on March 5, 2013 to Senate B&P Committee staff on this issue.

<u>ISSUE #14</u>: (BETTER USE OF HEALTH CARE INFORMATION.) Should the MBC engage stakeholders to identify areas in which alternative approaches may be used to analyze current data collected on healthcare facilities and practices in order to improve or enhance the practice of health care providers?

<u>Background</u>: The federal American Recovery and Reinvestment Act (ARRA), enacted by Congress in 2009, calls for the development of a nationwide health information technology infrastructure. To support its development, ARRA created the State Health Information Exchange Cooperative Agreement Program (HIE), which provides federal funding to states and "state-designated entities" to establish and implement statewide HIE networks.

HIE is defined as the mobilization of health care information electronically across organizations within a region, community or hospital system. The goal of the HIE is to facilitate access to and retrieval of clinical data to provide safer and timelier, efficient, effective, and equitable patient-centered care. The HIE is also useful to public health authorities to assist in analyses of the health of the population. The systems also facilitate the efforts of physicians and clinicians to meet high standards of patient care through electronic participation in a patient's continuity of care with multiple providers.

In addition to the HIEs, various Federal agencies and insurance companies require hospitals to collect patient satisfaction data among other data. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also requires hospitals to submit data on patient satisfaction as part of the re-accreditation process.

In light of the national focus on the use of health information technology, as well as the requirements of JCAHO and insurance companies, it is prudent that California begin to explore ways to utilize the aggregate data that is being collected to examine health care patterns across the state.

Staff Recommendation: Recommend that the MBC take steps toward creating a Task Force to discuss how aggregate data can be utilized for each task force member's respective purposes. The group would be requested to examine the aggregate data already required to be reported to federal government in order to identify trend lines across the state. Ultimately, these findings could be used to identify standards for best practices. Task force members may include the following:

- Medical Board of California
- California Hospital Association
- Institute for Medical Quality
- Joint Commission on Accreditation of Health Care Organizations
- Department of Public Health
- Institute for Population Health Improvement
- Citizen Advocacy Center
- Center for Public Interest Law

### MBC Response (April 2013):

Senate B&P Committee Staff has recommended that the MBC take steps to create a Task Force to discuss how clinical care aggregate data reported to the federal government by health care facilities can be utilized in order to identify trend lines and health care patterns across the state. The MBC has not discussed and taken a position on this proposal. The MBC would need to examine how this fits within the mission and role of the MBC. In addition, the MBC does not have oversight over the health care facilities that are collecting this data. The MBC may consider participation in such a task force, but it may not be the appropriate agency to lead this broad public health effort, as the MBC is a regulatory agency with accountability for the oversight of individual physician practice and behavior, without the resources or knowledge base to evaluate the performance of health systems in California.

ISSUE #15: (ADOPTION OF UNIFORM SUBSTANCE ABUSE STANDARDS.) Has the MBC adopted all of the Uniform Standards developed by the Department of Consumer Affairs Substance Abuse Coordination Committee? If not, why not?

**Background:** The Medical Board of California (MBC) operated a physician's substance abuse "Diversion Program" for 27 years, which utilized statutory authority granted to "divert" a physician into the Diversion Program for treatment and rehabilitation in lieu of facing disciplinary action. In 2007, the Diversion Program was terminated following the release of several audits exposing the egregious shortcomings of the program, which in many cases put patients at tremendous risk. Since the end of the diversion program, physicians dealing with alcohol or substance abuse issues, mental illness, or other health conditions that may interfere with their ability to practice medicine safely can seek private treatment and monitoring services. However, California is one of only 5 states in the United States that does not have a physician health program to coordinate and provide care and referral

services for physicians suffering from these maladies.

The Legislature enacted SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) to establish within the DCA a Substance Abuse Coordination Committee (SACC) to develop uniform standards and controls for healing arts programs dealing with licensees with substance abuse problems by January 1, 2010. SB 1441 requires each healing arts board within the Department to use the uniform standards developed by SACC regardless of whether the board has a formal diversion program.

The SACC completed its work and developed uniform standards in 16 specific areas identified by SB 1441. The uniform standards were published in April 2011. Since that time various boards within DCA have struggled with the uniform standards. Some boards have been reluctant to adopt the standards, contending that the standards are optional, or that certain standards are not applicable.

However, the Legislative Counsel, in a written opinion titled Healing Arts Boards: Adoption of Uniform Standards (# 1124437) dated October 27, 2011, states: "[W]e think that the intent of the Legislature in enacting Section 315.4 was not to make the uniform standards discretionary but to 'provide for the full implementation of the Uniform Standards' . . . Accordingly, we think the implementation by the various healing arts boards of the uniform standards adopted under Section 315 is mandatory."

An Attorney General Informal Legal Opinion, February 29, 2012, and a DCA Legal Counsel Opinion, dated April 5, 2012 both agree with this opinion.

The MBC has not yet adopted the Uniform Standards. At its January 31, 2013 Enforcement Committee meeting, the staff assessment of the Uniform Standards was that 8 of the 16 standards did not apply to the MBC, since they specifically reference a diversion program or elements typically found in a diversion program. Ultimately, the Enforcement Committee did not move forward on the proposal, choosing instead to have staff draft a more complete plan to implement the Uniform Standards.

<u>Staff Recommendation</u>: The MBC should fully implement the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees as required by SB1441. The MBC should report back to the Committee by July 1, 2013 of its progress in implementing the Uniform Standards.

### MBC Response (April 2013):

The MBC has and will fully implement the uniform standards that apply to the MBC. The MBC adopted regulations that were effective in July 2012 that adopted several of the uniform standards, including cease practice orders for positive tests. At the MBC's last Enforcement Committee Meeting, the Committee Chair requested that staff bring back for discussion, the issue of implementation of all uniform standards. These standards will be discussed at the April Enforcement Committee Meeting in Los Angeles. The MBC will report back to the Committee on the outcome of this meeting and the MBC's plan for full implementation of the uniform standards.

**ISSUE #16**: Stipulated settlements below the Disciplinary Guidelines.

**Background:** In October 2012, an investigative report by the *Orange County Register* (Register) found that from July 2008 to June 2011, the MBC settled with disciplined physicians for penalties or conditions which were below the MBC's own Disciplinary Guideline standards. In the negotiated settlements, which were the focus of the investigation, the *Register* found 62 of 76 cases in which patients had been killed or permanently injured had negotiated settlements with physicians. According to the *Register*, 63% of those cases were settled for penalties below the Board's own minimum recommendations under its Disciplinary Guidelines.

Often times licensing boards 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 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."

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.

Each board adopts disciplinary guidelines through its regulatory process. Consistent with its mandated priority to protect the public, a board establishes guidelines that the board finds appropriate for specific violations by a licensee.

The disciplinary guidelines are established with the expectation that Administrative Law Judges hearing a disciplinary case, or proposed settlements submitted to the board 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. However when there are factors that cause the discipline to vary from the guidelines, they should be clearly identified in order to ensure that the interest of justice is being served.

Staff Recommendation: The MBC should discuss with the Committee its policies regarding stipulated settlements and the reasons why it would settle a disciplinary case for terms less than those stated in the Board's Disciplinary Guidelines. What is the consumer protection rationale for settling administrative cases for terms that are below those in the Disciplinary Guidelines? Are these recommendations of the Attorney General's Office or decisions made by the MBC staff independent of the AG?

### MBC Response (April 2013):

The MBC uses the disciplinary guidelines as a framework for determining the appropriate penalty for charges filed against a physician. Business and Professions Code section 2229

identifies that protection of the public shall be highest priority for the MBC, but also requires that wherever possible, the actions should be calculated to aid in the rehabilitation of the licensee. While the disciplinary guidelines frame the recommended penalty, the facts of each individual case may support a deviation from the guidelines. Once the administrative action has been filed, existing law (Government Code Section 11511.5 and 11511.7) requires that a prehearing conference be held to explore settlement possibilities and prepare stipulations, as well as a mandatory settlement conference, in an attempt to resolve the case through a stipulated settlement before proceeding to the administrative hearing.

The Deputy Attorney General (DAG) responsible for prosecuting the MBC's case prepares a settlement recommendation that outlines the strengths and weaknesses of the MBC's case. The DAG will use the MBC's disciplinary guidelines to frame the recommended penalty, based upon what violations can be proven. The DAG negotiates to settle a case with a recommended penalty, but may ask the MBC representative for authority to reduce the penalty based on evidentiary problems; this type of negotiation is similar to what happens in criminal cases. In the negotiations to settle a case, public protection is the first priority, and must be weighed with rehabilitation of the physician.

When making a decision on a stipulation, the MBC is provided the strengths and weaknesses of the case, and weighs all factors. The settlement recommendations stipulated to by the MBC must provide an appropriate level of public protection and rehabilitation. Settling cases by stipulations that are agreed to by both sides expedites the rehabilitation of physicians and ensures consumer protection by 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 the MBC more timely than if the matter went to hearing. Currently, approximately 70% of cases are settled by stipulation. The MBC does not believe at this time any changes are needed in the way it approaches stipulated settlements, as consumer protection is always the MBC's primary mission.

# <u>ISSUE #17</u>: (CPEI IMPLEMENTATION.) Why has the MBC not filled staffing positions provided under CPEI in FY 2010-11?

Background: In response to a number of negative articles about the length of time licensing boards take to discipline licensees who are in violation of the law, in 2010, the DCA launched the Consumer Protection Enforcement Initiative (CPEI) to overhaul the enforcement process of healing arts boards. According to the DCA, the CPEI is a systematic approach designed to address three specific areas: Legislative Changes, Staffing and Information Technology Resources, and Administrative Improvements. Once fully implemented, the DCA expects the healing arts boards to reduce the average enforcement completion timeline to between 12 - 18 months. The DCA requested an increase of 106.8 authorized positions and \$12,690,000 (special funds) in FY 2010-11 and 138.5 positions and \$14,103,000 in FY 2011-12 and ongoing to specified healing arts boards for purposes of funding the CPEI. As part of CPEI, the MBC was authorized to hire 22.5 positions, including 20.5 (non-sworn) special investigators and 2 supervisors/managers.

However, the MBC has had very little success in filling these positions. An MBC staff report dated January 11, 2013, indicates that of the 22.5, positions authorized in 2010, 2.5 allocated for the MBC performing investigations for the Osteopathic Medical Board and the Board of

Psychology were transferred to those boards. Of the remaining positions, 2 were filled – a manager and an analyst in its CCU. This left the MBC with 18 unfilled CPEI positions.

According to the MBC the statewide budget crisis severely impacted its efforts to fill the remaining CPEI positions. Workforce cap position reductions, statewide hiring freeze, elimination of position due to a statewide mandate for a 5% salary saving reduction effectively eliminated all of the remaining CPEI positions.

In 2012, the MBC states that it was notified that it could reestablish the positions in the temporary help blanket as long as the Board always maintains a 5% vacancy rate to meet the required salary reduction level, and the MBC began the process of identifying positions to establish and hiring to fill those positions.

The MBC has determined that it will request the re-establishment of 14.5 positions in the following areas in order to improve the enforcement timeframes as originally planned in the CPEI. According to the staff report, the MBC has determined where those positions will be allocated to meet the demands of CPEI.

It is troubling to Committee staff that the MBC has not done more to fill these positions. It is the understanding of staff that the hiring freeze did not apply to filling the positions established by the CPEI BCP. If this is the case, why did the MBC not fill the positions or purse exemptions to the existing hiring restrictions?

In addition, the BCP authorized the MBC to hire 20.5 non-sworn special investigators. It is understood by the Committee that MBC staff may have some reluctance to hire non-sworn personnel to assist in investigations when the board's enforcement unit has been typically staffed with sworn (peace officer) investigators. However, if the reluctance to fill positions authorized by the Legislature is because the positions are not of the traditionally desired classification, it calls into question the management of the MBC, and whether the MBC is flaunting the will of the Legislature and undermining public protection. Clearly the Legislature expected that the boards would immediately fill these positions once approved by the Administration. Considering some of the major enforcement problems which have been identified regarding this Board, both in the media, by consumer advocates and by this Committee, and some of those problems being directly related to staffing issues, it seems completely inappropriate that this Board would stall for any reason in the hiring of additional investigators. It raises the question to what extent will the remaining CPEI positions, and the functions that the MBC intends for them to carry out, enable the MBC to achieve the goals established by CPEI?

<u>Staff Recommendation</u>: The MBC should update the Committee on the current status of its efforts to fill the CPEI positions. The MBC should further advise the Committee of the appropriate level of staffing necessary to implement the goals of CPEI.

### MBC Response (April 2013):

The MBC originally received 22.5 CPEI positions effective fiscal year (FY) 2010/2011. The MBC began to fill these positions by hiring an additional manager and one Staff Services Analyst in the Central Complaint Unit. This left the MBC with 20.5 CPEI positions. As stated above there were several factors that impeded the filling of these remaining positions.

Because the MBC conducted investigations for the Osteopathic Medical Board of California (OMBC) and the Board of Psychology (BOP), 2.5 of the CPEI positions authorized for the MBC were to assist in those boards' investigations. However, these boards determined that they would rather have the positions under their specific authority. Therefore, in FY 2011/2012, those 2.5 positions were taken from the MBC and provided to the OMBC and the BOP. This left the MBC with 18 CPEI positions.

The MBC began to develop a plan to hire non-sworn investigators and initiated the process to write duty statements and justifications to establish these positions. However, during FY 2010/2011, the MBC was required to decrease its positions due to a requested workforce cap drill. The MBC therefore did not move to fill any of its positions due to the uncertainty of the number of positions it would lose. The final direction on how many positions the MBC would lose due to the workforce cap (2.5 positions) was not provided to the MBC until June 2011. With the loss of these 2.5 positions, the MBC had 15.5 remaining CPEI positions.

The MBC was notified it could re-class some of the CPEI positions and again the MBC began to identify where to establish these 15.5 positions and into which classification to best address the needs of the MBC and to enhance consumer protection. However, the MBC was also under a hiring freeze, which required the MBC to request hiring freeze exemptions for any position the MBC wanted to fill, including CPEI positions. The MBC had to set priorities in submitting freeze exemptions. The MBC had several existing investigator and medical consultant positions that were vacant and therefore requested exemptions for these classifications in order to continue to process investigations. Additionally, there were several licensing positions that were vacant. The MBC determined that exemptions for the existing vacancies with a pending workload were higher priority than the establishment of new positions.

The hiring freeze was lifted in November of 2011 and the MBC again began discussion to fill the CPEI positions. However, in early 2012, the MBC was notified that it would be required to eliminate 18.1 positions due to the 5% salary savings reduction. Rather than eliminate existing staff or investigator positions, the MBC used the 15.5 vacant CPEI positions (and 2.6 other vacant positions) to meet the reduction requirement.

Although the MBC no longer has the CPEI positions, it was notified in September 2012 that it could reestablish these positions in the temporary help blanket as long as the MBC always maintains a 5% vacancy rate to meet the required salary reduction level. The MBC identified a plan to reestablish 14.5 positions into classifications that would best meet the needs of the MBC. Specifically, the MBC determined the need to address the loss of investigator positions in the district offices to meet the concept of the CPEI with the intent to lower the enforcement timeframe and improve consumer protection. This plan was presented to and approved by the MBC, and also included in the MBC's Supplemental Sunset Report. The MBC had submitted the appropriate paperwork to the Department of Consumer Affairs to fill 11 of these positions. However, the MBC was recently notified by DCA that the CPEI positions cannot be reclassified and can only be filled with non-sworn special investigators. The MBC will work on a plan to identify the functions that can be performed by these individuals in non-sworn positions within the constraints of law. Once this is done, it will submit paperwork to fill the

positions in an effort to reduce the enforcement timeframes and continue to improve consumer protection.

The MBC Executive staff is of the opinion that a reduction in an investigator's workload will assist the MBC in meeting the goals of the CPEI. The MBC staff identified a means to obtain additional investigator positions without an increase in budget authority via the reclassification of these positions. The plan identified in the MBC's Supplemental Sunset Report identified the manner in which the CPEI positions could be reclassified in order to meet the goals of the CPEI, ultimately reducing the time it takes to investigate a physician who is found to be in violation of the law.

## **ISSUE #18**: Reporting of Patient Deaths to the MBC.

<u>Background</u>: BPC § 2240 requires any physician and surgeon who performs a scheduled medical procedure outside of a general acute care hospital, as defined, 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, shall report, in writing on a form prescribed by the board, that occurrence to the board within 15 days after the occurrence.

In its Report, the MBC states that is concerned that it may not be receiving the reports from physicians as is required by statute because the number of patient death reports filed each year is very low. The MBC indicates that there is no way to currently verify if the Board receives 100% of the reports but those that are provided are submitted within the 15-day statutory timeframe. The Board has the authority to issue a citation to the physician for failing to file a report as required. The Board can also charge the failure to file the report as a cause of action in any administrative action being taken against the physician regarding the incident. The MBC states that it reminds physicians of their mandated reporting obligations in the quarterly Newsletter.

The MBC should inform the Committee how many deaths were reported pursuant to this section. Additionally, the MBC should take steps to inform, not only <u>licensees</u> but also <u>accrediting agencies</u> that accredit outpatient settings that this requirement exists. The Board should further coordinate with accrediting agencies how this requirement can be incorporated in the accrediting agencies' inspection reports of outpatient settings.

<u>Staff Recommendation</u>: The MBC should inform the Committee how many deaths were reported pursuant to Section 2240. Additionally, the MBC should take steps to inform, not only licensees but also accrediting agencies that accredit outpatient settings about the reporting requirement in Section 2240. MBC should also coordinate with accrediting agencies how this requirement can be incorporated in the accrediting agencies' inspection reports of outpatient settings.

### MBC Response (April 2013):

Business and Professions Code section 2240 requires physicians who perform medical procedures outside of a hospital (in outpatient surgery settings) that result in a patient death, to report to the MBC within 15 days. The number of reports received pursuant to section 2240 are reported in the MBC's Annual Report. In FY 2011/12, the MBC received seven (7)

reports. The MBC does list all mandated reports for physicians in the January issue of the Newsletter every year, which goes out to all physicians, applicants and subscribers; the Newsletter is also posted on the home page of the MBC's Web site. Pursuant to Senate B&P Committee staff's recommendation, the MBC will work on informing the Accreditation Agencies (AAs) and discuss with the Agencies the desire to include this information in the outpatient setting inspection reports. The MBC will keep the Committee apprised of these discussions.

## **ISSUE #19**: There appears to be a low use of the MBC's Interim Suspension Authority.

<u>Background</u>: Government Code § 11529 authorizes the administrative law judge of the Medical Quality Hearing Panel in the Office of Administrative Hearings to issue an interim order suspending a license of a physician, or imposing drug testing, continuing education, supervision of procedures, or other license restrictions. Interim orders may be issued only if the affidavits in support of the petition show that the licensee has engaged in, or is about to engage in, acts or omissions constituting a violation of the Medical Practice Act or the appropriate practice act governing each allied health profession, or is unable to practice safely due to a mental or physical condition, and that permitting the licensee to continue to engage in the profession for which the license was issued will endanger the public health, safety, or welfare. When an ISO is issued, the MBC has 15 days to file and serve a formal accusation under the Government Code to revoke the license of the physician.

This interim suspension order (ISO) authority was the first of its kind for DCA's regulatory boards, and was established in 1990 by SB 2375 (Presley, Chapter 1597, Statutes of 1990). This provision was intended to immediately halt the practice of very dangerous physicians in egregious cases.

A number of the recent newspaper articles critical of the MBC's enforcement practices have highlighted the time it takes to remove a dangerous doctor from practice. Enforcement statistics from the MBC's sunset report show that for the last 3 fiscal years, an average of 23 ISOs or temporary restraining orders (TRO) have been issued.

	FY 2009/10	FY 2010/11	FY 2011/12
ISO & TRO Issued	19	22	28

In 2004, the MBC Enforcement Monitor's Initial Report stated: "MBC's enforcement output statistics indicate a troubling decline in the efforts to use the powerful ISO/TRO authority in the recent past. ISOs/TROs sought by HQE on behalf of the MBC diminished from a high of 40 in 2001–2002 to 26 in the 2003–04 fiscal year (a decline of 40%). Given the importance of these public safety circumstances, a decline in the use of these tools is a source of concern to the Monitor." Since that time, ISO/TROs have remained low. According to the MBC, it sought 36 ISOs in FY 2011/12 although there were only 28 granted.

In discussing the challenges faced with obtaining an ISO, regulatory boards often point out the level of standard that must be demonstrated to obtain the ISO, and the difficulty in filing a formal accusation within 15 days from the time the ISO is issued.

Committee staff raises the issue of whether there should be a lower standard in order for an ALJ to issue an ISO. Furthermore, should there be lengthier timeframes (longer than 15 days) for the filing of an accusation after an ISO has been issued? In addition, in cases where the MBC is seeking to simply restrict a physician's prescribing privileges (rather than suspend the entire license), it may be an appropriate consumer protection tool to lower the standard for obtaining an ISO and for lengthening the timeframes for filing an accusation against a physician.

<u>Staff Recommendation</u>: The MBC should inform the Committee of the reasons why it believes that the number of ISOs and TROs has remained low in recent years. The MBC should further advise the Committee on whether Government Code § 11529 should be amended to provide for changes to the ISO or TRO process, so that it may enhance its use by the MBC to quickly remove dangerous physicians from practice.

### MBC Response (April 2013):

In the Senate B&P Committee's background paper it stated that there has been a low use of Interim Suspension Orders (see above). However, it is important to point out that in addition to interim suspension orders (ISOs) and temporary restraining order (TROs), the MBC utilizes restrictions pursuant to Penal Code 23, which are issued as part of a criminal hearing process, as a condition of bail. Restrictions are also imposed via a stipulated agreement to not practice or a stipulated agreement to a restriction. The MBC can also require physicians to cease practice if they fail to comply with a term or condition of their probation. In 2001/02, a total of 42 of these suspensions/restrictions were issued. This has remained fairly constant over the years, and for last fiscal year, 2011/12, again a total of 42 of these suspensions/restrictions were issued.

An ISO is considered extraordinary relief and pursuant to Government Code section 11529, a standard of proof must be met in order for an ISO to be granted. Since every case presents its own set of circumstances, it is difficult to generalize why an ISO is not currently in place for a particular licensee. Before an ISO can be requested, there are a number of steps that must be taken (gathering medical records, obtaining patient consent, medical consultant review, etc.) in order to prove that a licensee's continued practice presents an immediate danger to public health, safety, or welfare. Once the investigation progresses and the Attorney General's office reviews the case, a determination is made as to whether there is enough evidence to warrant requesting an ISO, which must be granted by an Administrative Law Judge (ALJ). Even after the ISO is requested, if an ALJ determines there is insufficient evidence, the ISO request can be denied. Due diligence must be taken to ensure that seeking an ISO is the correct course of action.

There is a 15-day time restraint in existing law to file an accusation after being granted an ISO, and a 30-day time restraint between the accusation being filed and a hearing being set. This means an investigation must be nearly complete in order to petition for an ISO. At this time, the MBC has not identified, discussed, or taken a position on any potential modifications or enhancements to the existing statutes for ISOs. This matter would be an issue for all boards within the Department of Consumer Affairs. The MBC believes that any avenue that would provide more consumer protections is warranted.

# <u>ISSUE #20</u>: Use of MBC's Authority to cite and fine physicians who fail to produce records within 15 days.

<u>Background</u>: In the 2005 JCBCCP review of the MBC, the issue of physicians withholding records in violation of BPC § 2225 was raised. Physicians have 15 days from the time they receive a patient's signed release to turn those medical records over to the MBC for its investigation of complaints. Subsequently, SB 231 amended Section 2225 to authorize the MBC to use its cite and fine authority for a physician for failure to provide requested records within the 15-day time period.

It is unclear whether the MBC has used this authority and whether this authority has proven helpful in obtaining physician compliance.

<u>Staff Recommendation</u>: The MBC should inform the Committee of its use of cite and fine authority under BPC § 2225. How many citations have been issued? What are the fine amounts that have been assessed? How has this authority worked to obtain compliance with the 15 day record production requirement?

### MBC Response (April 2013):

The MBC has utilized its authority to issue citations for failing to provide medical records to the MBC when provided with the patient's authorization for medical records. Since 2008, 19 citations have been issued with a standard fine amount for each citation of \$1000.

It is important to remember that a citation can only be issued for those cases where the MBC has the patient authorization to release the medical records. In most cases, the citations are issued in conjunction with a complaint undergoing the initial review in the Central Complaint Unit. In 2006, a citation was issued to a physician for failing to respond to the MBC's request for records on two patients. The physician failed to respond to the citation and the matter was referred for administrative action and the physician was ultimately assessed at fine of \$244,000 for failing to provide medical records to the MBC. The case underwent a number of appeals and was ultimately resolved in 2008. As a result of the lessons learned in that case, the Central Complaint Unit revised their methods of documenting evidence of noncompliance before a case is referred for a citation. The MBC's current protocol requires two written notifications to the physician and a phone conversation directly with the physician before a citation can be issued. While the number of citations may be limited to 3-4 per year, the goal is to ensure that the physician provides records timely to the MBC and that goal is being accomplished, as evidenced in the decrease in processing time in the Central Complaint Unit.

## <u>ISSUE #21</u>: Require Coroner Reporting of Prescription Drug Overdose Cases to the MBC.

**Background:** The epidemic of prescription drug overdoses is plaguing the nation and the number of deaths related to prescription drugs is overwhelming. At a time when the Board believes it should be receiving more coroner reports than ever, the number of reports received is at an all-time low. Only four reports were received in FY 2011/2012, and only one of the reports indicated a drug related death.

A recent *LA Times* series that analyzed coroners' reports for over 3000 deaths occurring in four counties (Los Angeles, Orange, Ventura and San Diego) where the cause of death was overdose by prescription drugs. The analysis found that in nearly half of the cases where prescription drug overdose was listed as the cause of death, there was a direct connection to a prescribing physician. The report also found that more than 80 of the doctors whose names were listed on prescription bottles found at the home of or on the body of a decedent had been the prescribing physician for 3 or more dead patients, including one doctor who was linked to as many as 16 dead patients.

The Board has reason to believe numerous deaths have occurred in the state that are related to prescription drug overdoses. However, complaints regarding drug-related offences are often hard for the Board to obtain. In most instances, patients who are receiving prescription drugs in a manner that is not within the standard of practice are unlikely to make a complaint to the Board.

BPC § 802.5 requires a coroner to report to the Board when he/she receives information based on findings by a pathologist indicating that a death may be the result of a physician's gross negligence or incompetence.

This section requires the coroner to make a determination that the death may be the result of a physician's gross negligence or incompetence. In order to alleviate the coroners from making this determination in prescription drug overdose cases, <u>all</u> deaths related to prescription drug overdoses should be reported to the Board for further investigation. This would allow the Board to review the documentation to determine if the prescribing physician was treating in a correct or inappropriate manner. This would increase consumer protection and ensure the Board is notified of physicians who might pose a danger to the public so action can be taken prior to another individual suffering the same outcome.

The Board recommends that BPC § 802.5 be amended to require coroners to report all deaths related to prescription drugs to the Board.

SB 62 (Price) was introduced on January 8, 2013, and would expand the coroner reporting requirement to further require that a coroner to file a report with the MBC when the coroner receives information that is based on findings by, or documented and approved by a pathologist that indicates that a death may be the result of prescription drug use.

This proposed change would help to connect the dots and create a very necessary pathway for prescription drug overdose deaths to be reported directly to the MBC and other health care boards that can take necessary action against their licensees who may have been directly involved. If boards are receiving reports from coroners throughout the state, they will be better armed with the necessary tools to make a correlation to their licensees in overprescribing circumstances and take action.

The provisions of SB 62 are consistent with the recommendation made in the MBCs report.

<u>Staff Recommendation</u>: Statutory changes should be made to require a coroner to file a report with the MBC and any other relevant health care boards when the coroner receives information that is based on findings by, or documented and approved by a

pathologist that indicates that a death may be the result of prescription drug use. MBC should also inform all coroners in the state about any statutory changes to the coroner reporting requirements.

### MBC Response (April 2013):

The MBC is supportive of SB 62 (Price), which will require deaths related to prescription drug use to be reported to the MBC. The MBC believes this bill will increase consumer protection and ensure the MBC is notified of physicians who might pose a danger to the public, so disciplinary action can be taken by the MBC. It is imperative that the MBC know about these cases. If SB 62 is signed into law, the MBC will ensure that coroners are informed of their new reporting requirements. The MBC attempts to notify all reporters of their reporting requirements on an annual basis. With the new Public Information Officer in place, the MBC will enhance its notification to groups like coroners and court clerks.

## <u>ISSUE #22</u>: Controlled Substance Utilization Review and Evaluation System (CURES) and California Prescription Drug Monitoring Program (PDMP) Funding.

**Background:** In 1997, California established an automated prescription monitoring program (also known as CURES) within the DOJ, Bureau of Narcotic Enforcement, that required the electronic reporting of Schedule II drugs prescribed by physicians and dispensed by pharmacies. The goal was twofold; to assist law enforcement agencies in identifying possible drug diversion and to assist regulatory agencies in identifying prescribers who may be prescribing excessive medications to the public.

Since 2003, physicians have been able to obtain "patient history" or activity reports from DOJ to assist in identifying those patients who may be "doctor shopping" or may have altered the quantity of drugs prescribed from the original order. "Doctor shoppers" are prescription-drug addicts who visit dozens of physicians and emergency rooms to obtain multiple prescriptions for drugs. It was felt that if physicians and pharmacies had real-time access to controlled substance history information at the point of care it would help them make better prescribing decisions and cut down on prescription drug abuse in California. The Patient Activity Reports (PAR) were generated from DOJ after the physician made a written request for the report.

In 2005, SB 151 expanded the reporting to CURES to include any prescriptions dispensed for Schedules II and III. Reporting for Schedule IV prescriptions was added shortly thereafter. The CURES database grew to contain over 100 million entries of controlled substance drugs that were dispensed in California and DOJ responded to over 60,000 requests from practitioners and pharmacists for PARs.

In 2009, DOJ launched an online PDMP database to provide real-time access to PARs. The on-line system made it easier for physicians to track their patients' prescription-drug history and provided health professionals, law enforcement agencies, and regulatory boards with faster computer access to patients' controlled-substance records. Under the new system, a pain-management physician examining a new patient complaining of chronic back pain would be able to look up the patient's controlled-substance history to determine whether the patient legitimately needed medication or was a "doctor shopper". In the past, the physician's request would have taken several days for a response from DOJ. With the new on-line system, physicians should have been able to identify "doctor shoppers" and other

prescription-drug abusers before they wrote them another prescription. Unfortunately, this system still needs to be upgraded to provide rapid response, made more user friendly, and available on the most up-to-date technology system (e.g. smartphone, tablet, iPad, etc.) in order to get the prescribers and dispensers who should be using the system, to actually use it in day-to-day practice.

The Budget Act of 2011 eliminated all general fund support of the CURES/PDMP, which included funding for system support, staff support, and related operating expenses. DOJ temporarily redirected 5 staff to maintain support for the system, which included such tasks such as processing new user applications, responding to emails and voicemails from users, etc. While 5 regulatory boards at the DCA provide some funding for system maintenance, the level of funding is inadequate to maintain a minimal functioning PDMP, and certainly not enough funding to enhance the system to meet today's demand.

With 7,500 pharmacies and 158,000 prescribers reporting prescription information annually, CURES is the largest online prescription-drug monitoring database in the U.S. Its goal is to reduce drug trafficking and abuse of dangerous prescription medications, lower the number of emergency room visits due to prescription-drug overdose and misuse, and reduce the costs to health care providers related to prescription-drug abuse.

Prescription-drug abuse costs the state and consumers millions of dollars each year and can have serious consequences for both abusers and the public. Each year, hundreds of people die from prescription-drug overdoses in California. A recent article published in the *American Medical News* indicates that real-time access to prescription drug monitoring program databases results in a sizeable drop in the number of inappropriate prescriptions written for opioids and benzodiazepines, according to a study in British Columbia.

The Board believes that maintaining and upgrading a CURES/PDMP is essential not only for the medical community utilizing the system but as a tool used by the regulatory boards to identify prescribers who are not providing California citizens with quality medical care and are contributing to the epidemic of prescription drug abuse in this State.

The MBC recommends that legislation be considered to provide an adequate funding source for CURES. The prescribers/dispensers should include physicians, dentists, pharmacists, veterinarians, nurse practitioners, physician assistants, osteopathic physicians, optometrists, podiatrists, pharmaceutical companies, and the public. This funding source should support the necessary enhancements to the computer system and provide for adequate staffing to run the system.

<u>Staff Recommendation</u>: The MBC should advise the Committee whether CURES is currently working for its investigatory and regulatory purposes. Does MBC query CURES as a tool in its investigations? Should it do so? MBC should provide an update on its usage by the Board, and how it can be improved. Does the MBC recommend that consideration should be given to using licensing fees of various health related boards to adequately funding CURES in the future and the these licensing boards have primary responsibility for any actions to be taken against its licensees?

#### MBC Response (April 2013):

The CURES Program is currently housed in the Department of Justice (DOJ) and is a state database of dispensed prescription drugs, some of which have a high potential for misuse and abuse. CURES provides for electronic transmission of specified prescription data to DOJ. In September 2009, DOJ launched the CURES Prescription Drug Monitoring Program (PDMP) system allowing pre-registered users, including licensed health care prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards, including the MBC, to access patient controlled substance history information through a secure Web site.

Since the inception of CURES, the MBC has utilized the reports available through the CURES data base as a valuable tool throughout the investigative process. As part of the intake or triage review of new complaints received in the MBC's Central Complaint Unit, when allegations of excessive or inappropriate prescribing are made, the prescriber history report is generated from CURES. The report provides the MBC with information on the quantity of prescriptions written by the physician, which can then be referred to a medical expert for review. The medical expert reviews the report to determine whether the quantity of medication being prescribed to a patient or patients is either appropriate or excessive and a field investigation can be initiated as a result. The medical expert also helps focus on specific patients who may be receiving a concerning amount or combination of controlled substances, as these patients generally do not complain to the MBC about the physician who is prescribing to them. The MBC's Central Complaint Unit also utilizes the CURES data base to evaluate complaints related to care being provided to specific patients; particularly when the complaint is made by a patient's family and if the patient refuses to provide an authorization for release of medical records. A patient activity report would be generated to identify whether the patient is receiving controlled substances from more than one prescriber or is receiving an excessive amount of controlled substances from a single provider. If deemed to be an issue, the MBC would then need to subpoena the medical records since an authorization for release could not be obtained from the patient.

When a case alleging inappropriate prescribing is sent from the MBC's Central Complaint Unit to the field, investigators will utilize the CURES reports for a variety of reasons. The investigator typically will initially run a CURES report that lists all patients to whom a physician is prescribing. The investigator will look for patients who reside far away from the physician's office or the pharmacy where prescriptions are being filled; patients who are using a variety of pharmacies to "cash" the prescriptions (this is done to avoid detection by pharmacy personnel); numerous people with the same surname receiving scheduled drugs from the same physician; and the combination of drugs being prescribed and the age of the patient. Once a sampling of patients who fit an aberrant prescribing pattern is identified, the investigator will then run the individual patient CURES report to learn of all the prescribers who are writing scheduled drugs to the patient. Investigators will then begin acquiring the information upon which a determination will be made whether or not the prescribing is within the standard of care.

Investigators also use CURES reports for cases alleging self-prescribing or physician impairment. In these instances, a CURES report is run for the individual physician to determine if he or she is receiving a concerning amount of prescriptions.

It is important to note that the CURES report does not stand alone as an investigative tool. It is a critical "roadmap" that leads the investigator to the evidence that ultimately will be utilized for prosecution, should that become necessary.

The MBC uses the CURES database to monitor physicians who have been placed on probation following disciplinary action for excessive or inappropriate prescribing. A common condition of probation ordered for inappropriate prescribing violations is to limit or restrict the controlled substances that a physician can prescribe. For example, a physician may be ordered to not prescribe Schedule II controlled substances during the period of probation. The MBC's Probation Unit will generate a report from CURES showing the physician's prescribing history in order to ensure that the doctor is complying with their probation condition. The Probation Unit can also order a patient activity report to ensure that physicians who are required to abstain from the use of controlled substances are not receiving or writing prescriptions in violation of this condition.

The MBC believes CURES is a very important enforcement tool, however the system needs to be fully funded and upgraded to be more real time and able to handle inquiries from all prescribers in California. The MBC has been very supportive in the past of any effort to get CURES more fully funded in order for the PDMP to be at optimum operating capacity.

As stated above, the MBC has supported in the past and recommends that legislation be considered to provide an adequate funding source for CURES. The funding should come from prescribers/dispensers (including physicians, dentists, pharmacists, veterinarians, nurse practitioners, physician assistants, osteopathic physicians, optometrists, and podiatrists), pharmaceutical companies, and the public.

## <u>ISSUE #23</u>: Exclude medical malpractice reports from requirements of a medical expert review by the MBC.

**Background:** The MBC has raised the following as a new issue in its Sunset Report. BPC § 2220.08 requires that before a quality of care complaint is referred for investigation it must be reviewed by a medical expert with the expertise necessary to evaluate the specific standard of care issue raised in the complaint. While, the rationale for the up-front specialty review makes sense, it may not make sense in the case of Medical Malpractice cases that have been reported to the Board.

The Board believes that medical malpractice cases reported pursuant to section 801.01 after the civil action has been concluded would be appropriate to exclude from the upfront specialty review as well. Unlike complaints filed by the public, medical malpractice cases have had the benefit of review by a number of medical experts. Typically both the plaintiff and the defendant will obtain an expert to review the care provided by the physician and opine as to whether the standard of care was met.

Whether the case settles prior to trial or proceeds through the litigation process, it has been subjected to numerous reviews, all by medical experts. The outcome from the medical malpractice case is required to be reported to the Board by the insurance carrier or employer who pays the award on behalf of the physician. According to the MBC, there is little benefit to

obtain an initial medical expert review on these cases and this additional review adds approximately two months to the time it takes to refer the case to investigation.

The Board recommends that medical malpractice reports be excluded from the requirements of section 2220.08 consistent with the exception made for reports filed pursuant to section 805.

<u>Staff Recommendation</u>: Legislation should be enacted to exclude medical malpractice reports from the requirements of a medical expert review under BPC § 2220.08.

#### MBC Response (April 2013):

The MBC agrees with Senate B&P Committee Staff's recommendation and submitted language on March 5, 2013 to Committee staff for this proposal.

### ISSUE #24: Require medical facilities to produce medical records within 15 days.

**Background:** The MBC has raised the following as a new issue in its Sunset Report. BPC § 2225.5 (a) (1) requires a licensee to produce the certified medical records of a patient, pursuant to the patient's authorization, within <u>15 business</u> days of the receipt of the request. However, subsection § 2225.5 (b) requires a facility <u>30 days</u> to produce the certified records. This disparity may have been seen as appropriate prior to the implementation of Electronic Health Records (EHR).

However, today most facilities (hospitals) maintain EHRs, which reduces the time required to retrieve and prepare medical records in response to requests. In an effort to reduce investigation time, consideration should be given to whether there is a need to allow a facility twice the amount of time to produce records than is allowed for production from the office of a licensee.

Additionally, if a subpoena duces tecum were served, the facility would have 15 days to produce the same records that they would be allowed 30 days to produce if requested via patient authorization. Therefore, the disparity should be eliminated and consistency established by affording 15 days for production of medical records by both the licensee and facilities.

The Board recommends that the law be amended to allow a facility only 15 days to provide medical records, upon request, if the facility has EHRs.

<u>Staff Recommendation</u>: BPC § 2225.5 (b) should be amended to require a facility to produce medical records within 15 days, if the facility has implemented Electronic Health Records (EHR).

#### MBC Response (April 2013):

The MBC agrees with Senate B&P Committee Staff's recommendation and has submitted language on March 5, 2013 to Committee staff for this proposal.

<u>ISSUE #25</u>: Consider requiring the Department of Public Health and hospital accrediting agencies to send reportable peer review incidents found during an inspection of the facility.

**Background:** The MBC has raised the following as a new issue in its Sunset Report. Pursuant to BPC § 805, certain peer review bodies must report actions pertaining to staff privileges, membership, or employment. Specifically, the chief of staff of a medical or professional staff or other a chief executive officer, a medical director or administrator of any peer review body, or a chief executive officer or administrator of any licensed health care facility or clinic must report the following within 15 days of the action:

- A peer review body denies or rejects a licensee's application for staff privileges or membership for a medical disciplinary cause or reason.
- A licensee's staff privileges, membership, or employment are revoked for a medical disciplinary cause or reason.
- Restrictions are imposed, or voluntarily accepted, on staff privileges, membership, or employment for a total of 30 days or more within any 12 month period for medical disciplinary reasons.
- A resignation, leave of absence, withdrawal or abandonment of the application or for the renewal of privileges occurs after receiving notice of a pending investigation initiated for a medical disciplinary cause or reason.
- A summary suspension of staff privileges, membership, or employment is imposed for a period in excess of 14 days.

The Board has noticed a decline in the number of 805 reports received, and indicated in the following chart:

	FY 01/02	FY 02/03	FY 03/04	FY 04/05	FY 05/06	FY 06/07	FY 07/08	FY 08/09	FY 09/10	FY 10/11	FY 11/12
805 reports received	151	162	157	110	138	126	138	122	99	93	114

The MBC suggests that the decline in reporting may be due to the fact the hospitals are finding problems earlier and sending physicians to remedial training prior to requiring 805 reporting. With the implementation of electronic health records and the mining of data, early identification is a real possibility. MBC further believes that the decline may also be due to hospitals not reporting.

However, because the Board does not have jurisdiction over the hospitals, it has no way of knowing the reason for the decline. The California Department of Public Health (CDPH) and other hospital accrediting agencies have the authority to review hospital records. In addition, these entities do inspections of the hospitals. If the CDPH had to send information to the Board based upon its inspections, it would allow the Board to review the information and determine if an 805 was received from the entity. If the Board did not receive the appropriate reporting, the Board would issue a fine to the entity and would also investigate the actions of the physician.

The MBC recommends amending existing law to require CDPH and hospital accrediting agencies to send reportable peer review incidents found during an inspection of the facility to the MBC. The MBC also recommends a requirement that these entities notify the Board if a hospital is not performing peer review.

Staff notes that since MBC is the agency with jurisdiction to enforce the peer review provisions, it may be appropriate for MBC to enter into an arrangement such as a memorandum of understanding (MOU) with CDPH and hospital accrediting agencies to have this information referred to MBC.

Staff Recommendation: The MBC should further discuss with the Committee the proposal, and consideration should be given to MBC entering into an arrangement or a MOU with CDPH and hospital accrediting agencies to send reportable peer review incidents found during an inspection of the facility to the MBC; and to further require that these entities notify the Board if a hospital is not performing peer review.

MBC Response (April 2013):

As stated above, the MBC has noticed a decline in the number of 805 reports received through the years. The decline in 805 reporting may be due to the fact the hospitals are finding problems earlier and sending physicians to remedial training prior to requiring 805 reporting or it may be due to hospitals just not reporting. However, because the MBC does not have jurisdiction over the hospitals, it has no way of knowing the reason for the decline. CDPH and other hospital accrediting agencies have the authority to review hospital records and conduct inspections of the hospitals.

The MBC does not believe that entering into an MOU would legally require these entities to provide the information to the MBC. The information obtained during an inspection is for the use of CDPH and the other hospital accrediting agencies and therefore, it may not be able to be provided to the MBC. Therefore, the MBC is recommending that existing law be amended to require state agencies and hospital accrediting agencies to send reportable peer review incidents found during an inspection of the facility to the MBC. The MBC submitted language on March 5, 2013 to Committee staff on this issue.

## **ISSUE #26**: Require that Expert Reviewer Reports be provided to the MBC in a timely fashion.

<u>Background</u>: The MBC has raised the following as a new issue in its Sunset Report. The Administrative Procedure Act (APA) includes limited discovery provisions that do not assist in discovering opposing expert information. The MBC states that in some instances, once the Board received this information, it has to amend the accusation and therefore increase the timeframe for administrative action. In the civil context, the best tool to find out information from opposing experts would be to depose the expert. However, the APA only allows depositions in extreme circumstances, which do not usually apply to Board cases (Government Code section 11511).

It may not be appropriate to amend and expand the discovery provisions under the APA, because the APA applies to all administrative hearings. Any modification to the APA exclusive discovery provisions would impact the disciplinary proceedings of other

administrative agencies and perhaps add costs and delays to these proceedings. The MBC recommends that instead of making any changes to the APA, the best way to make changes regarding expert testimony as it relates to MBC disciplinary cases is to amend BPC § 2334 which relates to expert testimony in disciplinary cases before the Board.

The MBC states that since its implementation, Section 2334 has been beneficial to the DAGs prosecuting Board cases. First, upon receipt of an expert witness disclosure, the DAGs can assess the qualifications of the respondent's expert in relation to the Board's expert.

Second, based upon respondent's brief narrative of his/her expert's opinions, the DAGs can provide that to the Board's expert to see if it changes his/her previously expressed opinions in the case. If it does change the Board's expert's opinion in a material way, the DAGs can reassess the settlement recommendation in the case and, with client approval, make a revised settlement offer. In this manner, Section 2334 directly promotes settlement in Board cases, which can often result in imposition of public protection measures in advance of the case proceeding to hearing.

Third, where cases do not settle, the brief narrative required by Section 2334 is also helpful to DAGs in preparing the Board's expert to testify at the administrative hearing. Fourth, by requiring respondents to confirm that their experts have, in fact, agreed to testify, Section 2334 helps to prevent defense counsel from listing various experts, who have not actually agreed to testify at the hearing. Finally, in those cases where respondents fail to make the required disclosures, their experts are routinely excluded. Since discovery is so limited in proceedings governed by the APA, section 2334 provides at least some information to the DAGs and the Board on this most important aspect of quality-of-care cases.

While section 2334 has been beneficial, the MBC believes it could be improved. The legislative history of section 2334 reveals that, during the legislative process, consideration was given to requiring both sides to exchange expert witness reports. The Board requires its own experts to prepare expert witness reports that, under the APA, must be produced in discovery. Requiring respondents to produce expert reports addressing each of the quality-of-care issues raised in the pending accusation would be of enormous benefit to the entire disciplinary process. It is believed that more cases would settle prior to hearing, thus avoiding the months of waiting by both sides while the parties await the commencement of hearings.

The deadline for both sides to make the required disclosures under section 2334 is only 30 calendar days prior to the commencement date of the hearing. That deadline is too late in the process and, as a result, can delay early settlement. If the date were, for example, 90 calendar days before the commencement date of the hearing or 180 calendar days after service of the accusation on respondent, then settlements may occur earlier, thus the imposition of public protection measures would occur sooner.

The term "commencement date" as used in Section 2334 should be defined and clarified. It should be the first hearing date initially set by OAH, regardless of any subsequent continuances of the hearing. There needs to be clarification on this term, since the MBC states that in one instance the Superior Court has construed the term to mean the date that opening statements are given. Such an interpretation makes the disclosure deadline a

"moving target" when hearings are delayed. This prolongs the entire administrative disciplinary process and delays consumer protection.

The Board recommends amending Section 2334 to require the respondent to provide the full expert witness report. Additionally, there needs to be specificity in the timeframes for providing the reports, such as 90 days from the filing of an accusation. This would provide enhanced consumer protection, as the physician who is found to be in violation of the law would be placed on probation, monitored, or sanctioned in a more expeditious manner, according to MBC.

Staff Recommendation: Consideration should be given to amending BPC § 2334 to: (1) require a respondent to provide the full expert witness report; (2) clarify the timeframes for providing the reports, such as 90 days from the filing of an accusation.

#### MBC Response (April 2013):

In an effort to enhance consumer protection, section 2334 of the Business and Professions Code should be amended as identified in the Senate B&P Committee staff's recommendation. The MBC submitted language on March 5, 2013 to Committee staff to clarify the date and require the complete expert report be produced by the respondent.

### **ISSUE #27**: Licensed Midwives: Physician Supervision.

**Background:** The MBC has raised the following as a new issue in its Sunset Report. BPC § 2057 authorizes a licensed midwife, under the supervision of a licensed physician and surgeon who has current practice or training in obstetrics, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care, for the mother and immediate care for the newborn. BPC § 2507(f) requires the MBC by July 1, 2003 to adopt regulations defining the appropriate standard of care and level of supervision required for the practice of midwifery. Due to the inability to reach consensus on the supervision issue, the MBC bifurcated this requirement and in 2006 adopted Standards of Care for Midwifery (CCR § 1379.19). Three previous attempts to resolve the physician supervision issue via legislation and/or regulation have been unsuccessful due to the widely divergent opinions of interested parties and their inability to reach consensus.

Although required by law, physician supervision is essentially unavailable to licensed midwives performing home births, as California physicians are generally prohibited by their malpractice insurance companies from providing supervision of licensed midwives who perform home births.

According to insurance providers, if physicians supervise, or participate, in a home birth they will lose their insurance coverage resulting in loss of hospital privileges. The physician supervision requirement creates numerous barriers to care, in that if the licensed midwife needs to transfer a patient/baby to the hospital, many hospitals will not accept a patient transfer from a licensed midwife as the primary provider who does not have a supervising physician. MBC states that California is currently the only state that requires physician supervision of licensed midwives. Among states that regulate midwives, most require some sort of collaboration between the midwife and a physician.

The MBC, through the Midwifery Advisory Council has held many meetings regarding physician supervision of licensed midwives and has attempted to create regulations to address this issue. The concepts of collaboration, such as required consultation, referral, transfer of care, and physician liability have been discussed among the interested parties with little success. There is disagreement over the appropriate level of physician supervision, with licensed midwives expressing concern with any limits being placed on their ability to practice independently. The physician and liability insurance communities have concerns over the safety of midwife-assisted homebirths, specifically delays and/or the perceived reluctance of midwives to refer patients when the situation warrants referral or transfer of care. MBC states that it appears the physician supervision requirement needs to be addressed through the legislative process.

In general, Committee staff agrees with the recommendation of MBC, noting that appropriate access to care, and patient safety would argue that an appropriate solution needs to be found regarding licensed midwife and physician supervision and/or collaboration.

<u>Staff Recommendation</u>: The MBC should reach a consensus with stakeholders on this important issue and then submit a specific legislative proposal to the Committee regarding the appropriate level of supervision required for the practice of midwifery.

#### MBC Response (April 2013):

The MBC agrees with the Senate B&P Committee staff's recommendation. The physician supervision requirement needs to be addressed through the legislative process, as many of the barriers to care identified by midwives focus around this one issue. AB 1308 (Bonilla) is a bill sponsored by the American College of Obstetricians and Gynecologists (ACOG). This bill requires the MBC to adopt regulations by July 1, 2015 defining the appropriate standard of care and level of supervision required for the practice of midwifery. The MBC will be actively working with ACOG and interested parties on the bill, as these issues need to be resolved in order to ensure consumer protection. The MBC will keep the Committee updated on its progress.

## **ISSUE #28**: Allow Licensed Midwives to have Lab Accounts and obtain Medical Supplies.

<u>Background</u>: The MBC has raised the following as a new issue in its Sunset Report. Licensed midwifes have difficulty securing diagnostic lab accounts, even though they are legally allowed to have lab accounts. Many labs require proof of physician supervision. In addition, licensed midwives are not able to obtain the medical supplies they have been trained and are expected to use: oxygen, necessary medications, and medical supplies that are included in approved licensed midwifery school curriculum (CCR § 1379.30). The inability for a licensed midwife to order lab tests often means the patient will not obtain the necessary tests to help the midwife monitor the patient during pregnancy. In addition, not being able to obtain the necessary medical supplies for the practice of midwifery adds additional risk to the licensed midwife's patient and child.

The MBC, through the Midwifery Advisory Council held meetings regarding the lab order and medical supplies/medication issues and has attempted to create regulatory language to address this issue. However, based upon discussions with interested parties it appears the

lab order and medical supplies/medication issues will need to be addressed through the legislative process.

<u>Staff Recommendation</u>: Legislation should be enacted to clarify that a licensed midwife may order laboratory tests, and obtain medical supplies. The MBC should submit a specific legislative proposal to the Committee regarding this recommendation.

#### MBC Response (April 2013):

The MBC agrees with the Senate B&P Committee staff's recommendation. The ordering of laboratory tests and obtaining of medical supplies by midwives needs to be addressed through the legislative process. AB 1308 (Bonilla) is a bill sponsored by the American College of Obstetricians and Gynecologists (ACOG). This bill would allow a Licensed Midwife to directly obtain supplies, order tests, and receive reports that are necessary to his or her practice of midwifery, consistent with the scope of practice for a Licensed Midwife. The MBC will be actively working with ACOG and interested parties on the bill, as this issue needs to be resolved in order to assist the Licensed Midwives in their practice of midwifery and to protect their patients. The MBC will keep the Committee updated on its progress.

### **ISSUE #29**: Clarify Midwifery education and clinical training.

Background: The MBC has raised the following as a new issue in its Sunset Report. BPC § 2514 authorizes a "bona fide student" who is enrolled or participating in a midwifery education program or who is enrolled in a program of supervised clinical training to engage in the practice of midwifery as part of that course of study if: (1) the student is under the supervision of a physician or a licensed midwife who holds a clear and unrestricted California midwife license and who is present on the premises at all times client services are provided; and (2) the client is informed of the student's status. There has been disagreement between the MBC and some members of the midwifery community regarding what constitutes a "bona fide student." The MBC believes the current statute is very clear regarding a student midwife.

Some members of the midwifery community hold that an individual who has executed a formal agreement to be supervised by a licensed midwife but is not formally enrolled in any approved midwifery education program qualifies the individual as a student in apprenticeship training. Many midwives consider that an individual may follow an "apprenticeship pathway" to licensure.

The original legislation of the Midwifery Practice Act, included the option to gain midwifery experience that will then allow them to pursue licensure via the "Challenge Mechanism" detailed in BPC § 2513 (a) which allows an approved midwifery education program to offer the opportunity for students to achieve credit by examination for previous clinical experience. According to MBC, this provision was included to allow for those who had been practicing to meet the requirements for licensure. The statute clearly states a midwife student must be formally enrolled in a midwifery educational institution in order to participate in a program of supervised midwifery clinical training. A written agreement between a licensed midwife and a "student" does not qualify as a "program of supervised clinical training". Accordingly, these types of arrangements are not consistent with the provisions of BPC § 2514. A Task Force consisting of members of the Midwifery Advisory Council has recently been formed to

examine this issue. However, the issue of students/apprenticeships may need to be addressed through the legislative process, according to MBC.

<u>Staff Recommendation</u>: Recommend legislation should be enacted to clarify when an individual is considered a bona fide student, and to clarify that a written agreement does not meet the requirement of a program of supervised clinical training. The MBC should submit a specific legislative proposal to the Committee regarding this recommendation.

### MBC Response (April 2013):

The MBC agrees with Senate B&P Committee Staff's recommendation and submitted language on March 5, 2013 to Committee staff for this proposal.

### **ISSUE #30**: Clarify the role of a Midwife Assistant.

**Background:** The MBC has raised the following as a new issue in its Sunset Report. A concern revolves around the use of "assistants" by a licensed midwife and the duties the assistant may legally perform. It has been brought to the attention of the MBC that licensed midwives use midwife assistants. Currently, there is no definition for a midwife assistant, the specific training requirements or the duties that a midwife assistant may perform.

MBC states that the law does not address the use of a midwife assistant, the need for formal training or not, or the specific duties of an assistant. Current statute does not provide a licensed midwife with the authority to train or supervise a midwife assistant who is actually assisting with the delivery of an infant. The issue of a midwife assistant is not an issue that can be addressed with regulation with the current statutes that regulate the practice of midwifery. The issue of the midwife assistants should be addressed with legislation, according to MBC.

<u>Staff Recommendation</u>: The MBC should provide more information regarding the proposal to address the issue of midwife assistants in legislation.

#### MBC Response (April 2013):

The MBC agrees with the Senate B&P Committee staff's recommendation in that the issue of the midwife assistants should be addressed with legislation. However, the MBC needs to research and gather more information before it can make an informed decision on what the language regarding midwife assistants should include. The MBC will conduct this research and report back to Committee staff with more information on this issue, including suggesting language for legislation.

## **ISSUE #31**: SB 122 implementation for Out-of-State Licensed Physicians.

<u>Background</u>: SB 122 (Price, Chapter 789, Statutes of 2012), among other things, made clarifications to the licensing by MBC of physicians who have attended foreign medical schools. The bill was intended to address a concern by the Author that physicians who have been practicing in other states in good standing for many years were being refused a license to practice in California because the foreign medical school they attended has not been recognized by the MBC, even though it may have been recognized in another state. The

Author believed that the MBC should at least be able to have the discretion to review the practice and other qualifications of the physician and surgeon who has been practicing in another state, and make a determination whether they are competent to practice within California even though they may have attended a foreign medical school that is currently not on the MBC's approved list of medical schools.

The Author worked with the MBC in drafting the final amendments which went into the bill to provide the MBC with the tools it needs to license such physicians who had been practicing safely in other states for a number of years but who the MBC had refused to issue a license to because of attendance at an unrecognized medical school or at a disapproved medical school.

Ultimately the language identified by the MBC required a physician who had attended an unrecognized medical school must practice for 10 years in another state in order to become licensed in California, and a physician who had attended a disapproved medical school had to practice for 20 years in another state in order to become licensed in California.

Staff Recommendation: The MBC should advise the Committee of its implementation of SB 122. How many licenses have been issued under the new provisions? How does the MBC propose to handle those cases of physicians who have a mixed combination of medical education, having received part of their education at an unrecognized medical school, and part at a disapproved medical school? Does the MBC anticipate that regulations could authorize a physician with a mixed combination of education to become licensed under the 10 year requirement? Does the MBC think that further legislation is needed to clarify such cases?

#### MBC Response (April 2013):

SB 122 Price (Statutes 2012, Chapter 789) allows applicants who have attended and/or graduated from an unrecognized or disapproved school to be eligible for licensure in California if they have continuously practiced in another state for 10 years if they went to an unrecognized school, or 20 years if they went to a disapproved school. Following the letter of the law, if an individual completes any of his or her medical schooling at a disapproved school, the 20 year rule would apply. This bill allows the MBC to combine the period of time the applicant has held a license in other states and continuously practiced, but applicants shall have a minimum of five years of continuous practice and licensure in a single state. This bill specifies that continuous licensure and practice includes any postgraduate training after 24 months in a postgraduate training program. The applicant must also meet specified criteria in order to be eligible for licensure in California (must be certified by an ABMS specialty board; must have successfully completed the licensing examination required in existing law; must have successfully completed three years of postgraduate training; must not have any discipline on their license in another state or any adverse judgments or settlements relating to the practice of medicine; must not be subject to licensure denial; and must not have held a healing arts license that has been the subject of disciplinary action by a healing arts board of this state or by another state or federal territory).

In addition, SB 122 allows the MBC to adopt regulations to establish procedures for accepting transcripts, diplomas, and other supporting information and records when the originals are not available due to circumstances outside the applicant's control. This bill also allows the

MBC to adopt regulations authorizing the substitution of additional specialty board certifications for years of practice or licensure when considering the licensure of a physician and surgeon.

Before SB 122 was signed into law, if an individual attended and/or graduated from an unrecognized or disapproved international medical school, he/she would have not been eligible for licensure in California. The MBC previously did not recognize education acquired at an unrecognized or disapproved school as satisfying the standards set forth in the applicable statutes and regulations.

The language contained in SB 122 that was signed into law is the language drafted and supported by the MBC. The MBC supported this language because requiring 10 and 20 years of continuing practice in another state, among other requirements, are substantial enough to ensure consumer protection. In addition, allowing individuals that meet the requirements in this bill to be eligible for licensure in California, will provide another pathway for competent physicians to obtain a California license and serve patients in California.

For implementation, applications received that meet the requirements of SB 122 (Business and Professions Code section 2135.7) go to the MBC's Application Review Committee (ARC) to determine eligibility. To date, the MBC has received two applications pursuant to this new section (BPC 2135.7). One application has been reviewed by the ARC and the individual has been licensed. One application contained deficiencies that need to be resolved prior to processing.

The MBC also received two applications in which the applicant does not meet the criteria of B&P Code section 2135.7 at this time. Additionally, one previous applicant had requested an Administrative Hearing. The hearing was held and the final decision was to have the applicant reviewed by the ARC. The application is now complete and will be reviewed at the next ARC, to be held April 26, 2013.

At this time, the MBC only has only held one ARC, thus it is too early to determine the regulations that are needed until more applications are received pursuant to Business and Professions Code section 2135.7. Once the MBC starts receiving more applications and issues are determined, staff will work on identifying the need for regulations. This will most likely take place in summer/fall 2013 with discussion at the Licensing Committee. The MBC does not believe any statutory amendments need to be made at this time.

## <u>ISSUE #32</u>: Continued Utilization by the MBC of Vertical Enforcement Prosecution (VE).

**Background:** In 2005, SB 231 (Figueroa, Chapter 674, Statutes of 2005) created a pilot program establishing a vertical prosecution model, also known as vertical enforcement (VE) program to handle MBC investigations and prosecutions. VE requires Board investigators and Attorney General (AG) Health Quality Enforcement Section (HQES) prosecutors to work together from the beginning of an investigation to the conclusion of legal proceedings. The MBC and the HQES have used the VE program since 2006, and a number of modifications have been made since its inception to make the program more efficient.

In 2010, VE was extensively studied by Benjamin Frank, LLC. The report, titled *Medical Board of California – Program Evaluation* made several conclusions, including that the insertion of DAGs into the investigative process did not translate into more positive disciplinary outcomes or a decrease in investigation completion times, and recommended scaling back and optimizing DAG involvement in investigations. The AG's Office took great exception to certain portions of the report, namely the cost of VE in the investigation phase of the case and that greater DAG involvement under the VE model has not translated into greater public protection.

The MBC states that although the investigation timelines have shortened, it is unknown if this is due to VE or if it is due to increased efficiencies in enforcement processes and procedures in general. In order to more fully determine the level of success of the VE program, the MBC and the AG have engaged in discussions of the accumulated data from the VE cases. At this time, the analysis of the VE program by the MBC and the AG has not been fully completed. The Committee anticipates greater detail to be furnished by the Board and the AG's office later in 2013.

What MBC has concluded thus far is that significant improvements in actions taken have occurred and are identified below:

Comparing fiscal year (FY) 2006/2007 to FY 2011/2012:

- 47% more cases were referred to the Attorney General's Office,
- 74% more probation violation cases were referred to the Attorney General's Office.
- 49% more license restrictions/suspensions were imposed while administrative action was pending,
- 203% more cases were referred for criminal action,
- 35% more revocations were issued,
- 25% more cases resulting in probation were issued, and
- 26% more disciplinary actions were issued.

Committee staff anticipates hearing from the MBC and the AG as the sunset process moves forward. However, the VE program should continue and further ways should be explored to make the collaborative relationship between investigators and prosecutors more effective to carrying out a vigorous enforcement process to protect the public.

<u>Staff Recommendation</u>: Recommend continuing the VE program, and explore further ways to improve the collaborative relationship between investigators and prosecutors to improve the effectiveness of the MBC enforcement program.

#### MBC Response (April 2013):

As stated in Issue 9 above, the MBC believes that the benefits of VE are significant and does not believe that any legislative amendments need to be made at this time. The MBC recognizes there have been challenges in the implementation of VE, but those challenges can be overcome through continued collaboration between the MBC and HQES, and revisions to the procedural manuals used by both staffs. The MBC realizes the importance of the VE model and will continue to strive towards its improvement with the overall goal of meeting the MBC's mandate of consumer protection. The MBC looks forward to working with

the AG's Office to identify improvements that would further enhance collaborative efforts of both the MBC and the AG's Office.

<u>ISSUE #33</u>: Should the MBC's authority to issue a cease practice order be expanded to situations where in the course of a fitness to practice investigation a licensee refuses to undergo a duly ordered physical or mental health examination?

<u>Background</u>: Under BPC § 820, the MBC may order a physical or mental health examination of a licensee whenever it appears that a licensee's ability to practice may be impaired by physical or mental illness. The examination order is part of the investigation phase, and allows the MBC to make a substantive determination that the licentiate's ability to practice his or her profession actually has become impaired because of mental or physical illness.

Failure to comply with an examination order constitutes grounds for suspension or revocation of the individual's certificate or license (BPC 821). However, the process for suspension or revocation for refusal to submit to a duly-ordered examination can be lengthy, as demonstrated by a recent court case in which a licentiate of the Board of Registered Nursing refused a psychiatric examination yet continued to practice for months thereafter (see *Lee v Board of Registered Nursing*, 209 Cal. App. 4th 793; 147 Cal. Rptr. 3d 269; Sept. 26, 2012).

To refuse or delay compliance with an examination order poses risks for consumers because of the possibility that a mentally or physically ill practitioner could continue to see patients until the MBC completes suspension or revocation proceedings under BPC § 821. Public protection would be better served if the MBC has the authority to issue a cease practice order in cases where compliance with an examination order under BPC § 820 is delayed beyond a reasonable amount of time (perhaps 15-30 days).

<u>Staff Recommendation</u>: Recommend amendments to the MBC's authority to issue a cease practice order to expand to situations where in the course of a fitness to practice investigation a licensee refuses to undergo a duly ordered physical or mental health examination.

#### MBC Response (April 2013):

The MBC agrees with Senate B&P Committee staff's recommendation. Public protection will be better served if the statue is amended to give the MBC the authority to issue a cease practice order in cases where the licentiate delays or fails to comply with an order issued under Business and Professions Code section 820 within the specified time frame as set forth in the order. This does require a legislative change and language was submitted on March 5, 2013 to Senate B&P Committee staff to address this issue.

<u>ISSUE #34</u>: (REQUIREMENT FOR A FICTITIOUS NAME PERMIT.) Should the exemption for accredited outpatient settings to obtain a fictitious permit be removed?

<u>Background</u>: Current law requires that a physician and surgeon, whether as a sole proprietor, a partnership, group or professional corporation, who desires to practice in any other name must obtain and maintain a fictitious name permit that is issued by the MBC.

Additionally, BPC § 2285 provides that the use of any fictitious, false, or assumed name, or any name other than his or her own by a licensee either alone, in conjunction with a partnership or group, or as the name of a professional corporation, in any public communication, advertisement, sign, or announcement of his or her practice without a fictitious-name permit constitutes unprofessional conduct. This requirement does not apply to the following:

- Licensees who are employed by a partnership, a group, or a professional corporation that holds a fictitious name permit.
- Licensees who contract with, are employed by, or are on the staff of, any clinic licensed by the State Department of Health Services, as specified.
- An outpatient surgery setting granted a certificate of accreditation from an accreditation agency approved by the MBC.
- Any medical school approved by the MBC or a faculty practice plan connected with the medical school.

SB 100 required that as part of the accreditation process, the accrediting agency shall conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest therein, to determine whether there have been any adverse accreditation decisions rendered against them. For the purposes of this section, "conducting a reasonable investigation" means querying the MBC and the Osteopathic Medical Board to ascertain if either the outpatient setting has, or, if its owners are licensed physicians and surgeons, if those physicians and surgeons have, been subject to an adverse accreditation decision. Additionally, SB 100 required the MBC to obtain and maintain a list of accredited outpatient settings and notify the public by placing the information on the Internet Website. The information to be posted includes the name, address, and telephone number of any owners and their medical license numbers, and the name and address of the facility.

<u>Staff Recommendation</u>: In order for the public to get accurate information on outpatient settings that do business under a fictitious name, BPC § 2285 (c) should be amended to delete the exemption for outpatient settings that are accredited.

#### MBC Response (April 2013):

Existing law (Business and Professions Code section 2285) requires a licensee that uses fictitious, false, or an assumed name, or any name other than his or her own, to obtain a fictitious name permit (FNP). The purpose of a FNP is to allow a licensed physician and surgeon or podiatrist to practice under a name other than his or her own, while still allowing for the MBC and consumers to know the actual name of the individual that is associated with that fictitious name (that way a consumer can utilize the MBC's Web site to look up the physician's profile that is associated with the FNP). Currently, outpatient surgery settings are exempted from the requirement to obtain a fictitious name permit.

Committee staff has suggested in the background paper that existing law be amended to delete the exemption for outpatient settings that are accredited. However, this would not significantly increase consumer protection because a FNP is only issued to the <u>owner</u> of the facility, not to all physicians working in the facility. In addition, the Accreditation Agencies are

already mandated to obtain the name of the owners of an outpatient setting. Requiring these owners to also get a fictitious name permit duplicates information that is already gathered and will cost the licensee additional time and money. The MBC has not yet discussed or taken a position on this issue; however, MBC staff is willing to work with Committee staff to discuss this issue further. There may be other amendments that would be better to ensure consumer protection and meet the goal of identifying physicians in an outpatient surgery center. MBC staff commits to working with Committee staff on this issue.

## **TECHNOLOGY ISSUES**

## **ISSUE #35**: What is the status of BReEZe implementation by the MBC?

<u>Background</u>: The BreEZe Project will provide DCA boards, bureaus, and committees with a new enterprise-wide enforcement and licensing system. BreEZe will replace the existing outdated legacy systems and multiple "work around" systems with an integrated solution based on updated technology.

BreEZe will provide all DCA organizations with a solution for all applicant tracking, licensing, renewal, enforcement, monitoring, cashiering, and data management capabilities. In addition to meeting these core DCA business requirements, BreEZe will improve DCA's service to the public and connect all license types for an individual licensee. BreEZe will be web-enabled, allowing licensees to complete applications, renewals, and process payments through the Internet. The public will also be able to file complaints, access complaint status, and check licensee information. The BreEZe solution will be maintained at a three-tier State Data Center in alignment with current State IT policy.

BreEZe is an important opportunity to improve the BPM operations to include electronic payments and expedite processing. Staff from numerous DCA boards and bureaus have actively participated with the BreEZe Project. Due to increased costs in the BreEZe Project, SB 543 (Steinberg, Chapter 448, Statutes of 2011) was amended to authorize the Department of Finance (DOF) to augment the budgets of boards, bureaus and other entities that comprise DCA for expenditure of non-General Fund moneys to pay BreEZe project costs.

The MBC is scheduled to begin using BreEZe in the "Early Spring" of 2013. It would be helpful to update the Committee about MBC's current work to implement the BreEZe project.

Prior to the DCA BreEZe project, the Board determined that it was in need of a new information technology system that would allow data transfer with the Department of Justice (DOJ) as well as improve complaint processing. This Complaint Resolution Information Management System (CRIMS) would provide the Board with needed technological efficiencies that would assist in streamlining the enforcement process. The Board was beginning to develop requirements for this new system when the BreEZe project was initiated. Since the scope of the BreEZe project, which incorporated the requirements for CRIMS, was also a replacement of the Board's archaic licensing system, the Board stopped working on the CRIMS project and joined the DCA in working on the BreEZe project.

Staff Recommendation: The MBC should update the Committee about the current status of its implementation of BreEZe. What have been the challenges to implementing this new system? What are the costs of implementing this system? Is the cost of BreEZe consistent with what the MBC was told the project would cost? Will BreEZe interact with the AG's information technology to allow seamless and usable data to be transferred between the MBC and the DOJ?

#### MBC Response (April 2013):

The Department of Consumer Affairs is working on a project to replace the current licensing and enforcement legacy systems in addition to about 80 existing workaround databases. The MBC has been extremely involved in this project from its inception. The most significant challenges to implementing the system are: 1) testing the new system, 2) training the necessary staff, and 3) verifying the data being converted. These activities take a significant amount of staff time in addition to the regular day-to-day work of the MBC. The MBC in its original sunset report stated that it had already put over 10,000 staff hours into this project. Additionally, the MBC in its supplemental report estimated it would put 14,000 staff hours in prior to the implementation of the system. This number did not include the 3,768 hours so far spent in training nor the time staff will take to become fully knowledgeable of the system once it is implemented. The MBC has had staff do overtime in order to keep the current functions of the MBC while also having to perform the testing and data validation needed for the project.

The BreEZe project will cost the MBC approximately \$1.2 million dollars for each 5 years after the project is implemented. Based upon the funding structure for the project, the MBC does not have to pay until the implementation of the project. This cost is consistent with what the MBC was originally told. The MBC has been told that the BreEZe system has the capability of interacting with the Department of Justice's system in the sharing of data. However, this is not scheduled for the first two releases. It may occur in Release 3 or after the system completely roles out.

## <u>ISSUE #36</u>: (PUBLIC DISCLOSURE.) The limited ten year posting requirement for the MBC's Website should be removed.

**Background:** The MBC has raised the following as a new issue in its Sunset Report. BPC § 2027 was amended effective January 1, 2003 to require the Board to remove certain public disclosure information from its Website. Specifically, the amendment stated:

"From January 1, 2003, the information described in paragraphs (1) (other than whether or not the licensee is in good standing), (2), (4), (5), (7), and (9) of subdivision (a) shall remain posted for a period of 10 years from the date the board obtains possession, custody, or control of the information, and after the end of that period shall be removed from being posted on the board's Internet Website. Information in the possession, custody, or control of the board prior to January 1, 2003, shall be posted for a period of 10 years from January 1, 2003."

The information contained in these subsections pertaining to a physician's license, that would require removal, include: any license or practice suspension/restriction; any enforcement actions (e.g. probation, public reprimand, etc.); any disciplinary action in California or any

other state as described in BPC § 803.1; any current accusations; any malpractice judgment or arbitration award; any misdemeanor conviction that resulted in disciplinary action; and any information required pursuant to 803.1. The only items that would remain on a physician's profile on the Board's Website after ten years would be a felony conviction and hospital disciplinary action that resulted in termination or revocation of a physician's hospital staff privileges (unless those privileges were reinstated and then the information will only remain posted for 10 years from the date of restoration).

Although the statute requires the removal of the information from the Board's Website, these records are considered to be indefinitely public and therefore can be obtained from the Board's office via phone or in person. However, most members of the public would not know to call the Board unless they <u>fully</u> read and understood the Board's disclaimers. If the public does read the disclaimer and calls the Board, staff will copy the documents and provide them to the public.

The Board will begin the removal of the documents January 1, 2013. There are several concerns pertaining to the removal of this information. First, the MBC is unsure whether the removal of this information is beneficial to the public. In today's society, transparency is foremost in the public's mind. If the Board has information that it is not providing to the public in an easy to access format, the Board is not doing its due diligence related to transparency. No matter how many disclaimers the Board puts on its Website, and no matter how eye catching it may be, individuals have a tendency not to read the disclaimers. Therefore, the public will believe the physician he/she is looking up has never had any action taken by the Board. If a bad outcome occurs, and the individual subsequently finds that the Board had information but it wasn't posted on the physician's profile, this will raise concerns about the Board's effectiveness in protecting consumers.

Additionally, the MBC states that there is increased workload associated with the removal of this information. Currently, the Board receives very few requests for documents due to the fact the information is easily accessible and printable from the Board's Website. Once these documents are removed, if the public were to read the disclaimers, the Board's call volume will increase because the public will want to know whether there is information on a physician that "may" be available at the Board's headquarters, but cannot be posted on the Board's Website. This will result in additional inquiries to the MBC, and the workload associated with determining if there are documents available, making the copies, and either scanning and emailing the documents or mailing the documents (plus postage to mail).

While the MBC understands this information has an impact on a physician, the MBC also believes the public has the right to review the information and make its own decision regarding the physician based upon the circumstances of the case, including how long ago the action took place.

In addition, the statute provides that the information shall remain posted for 10 years from the date the MBC obtains possession, custody, or control of the information. However, this is vague. The MBC states that it is not sure if its interpretation of the law is what was intended by the Legislature. For example, for individuals who are placed on probation, the Board has interpreted the law to mean that the 10 years begins from the effective date of the decision and that would be when the information was in the Board's possession. If an individual were

on probation for 7 years, once probation was completed, the information would only be posted for those 3 additional years. The MBC states that it does not know if this was the Legislature's intention, or if the information should be posted for 10 years from the date the probation was completed. For malpractice judgments, the MBC interprets the law to mean the Board would keep this action on the Website for 10 years from the date the Board receives this information, not the date of the judgment. The MBC may not receive the information timely, and the judgment may have been issued a significant amount of time prior to the MBC's receipt, leading to inconsistency in how certain types of information is posted under the law.

The MBC recommends elimination of the 10 year posting requirement in order to ensure transparency to the public. The MBC further recommends that if the Legislature does not wish to eliminate the requirement for the 10 year posting, that it specify a date, or have the MBC do that in regulations, when the 10 years begins/ends for these cases.

Staff Recommendation: Recommend that in the interest of transparency and disclosure of information to the public, BPC § 2027 should be amended to remove the 10 year limit on how long information should be posted on the MBC's Internet Website.

#### MBC Response (April 2013):

The MBC agrees with the Senate B&P Committee staff's recommendation. In the interest of consumer protection, the MBC recommends elimination of the 10 year posting requirement in order to ensure transparency to the public; the MBC submitted language on March 5, 2013 to the Senate B&P Committee staff for this amendment.

# CONTINUED REGULATION OF THE PROFESSION BY THE CURRENT MEDICAL BOARD OF CALIFORNIA

<u>ISSUE #37</u>: Registered Dispensing Optician Program: Should the RDO Program be Transferred to Another State Agency?

<u>Background</u>: The MBC has raised the following as a new issue in its Sunset Report. The MBC regulates the allied health professions of registered contact lens dispensers, registered dispensing opticians, registered non-resident contact lens sellers, registered spectacle lens dispensers under the provisions of Chapter 5.5 of Division 2 of the BPC (Commencing with Section 2550) through the Registered Dispensing Optician Program (RDO Program).

In its Sunset Report, the MBC discusses transferring regulation of the RDO Program to another entity such as the State Board of Optometry (SBO) or to the Department of Consumer Affairs to be operated as a program, board or committee within the Department.

The MBC states that SBO reported it receives about 20-30 calls a month from consumers who believe they received services from an optometrist, when in reality they received services from an individual or business that is a registrant with the RDO Program. Almost all of these calls are complaint related and many times include a combination of issues which

also involve an optometrist and optometric assistant. Further, many consumers do not understand that the functions of the optometrist and the RDO are different. Unfortunately, consumers incorrectly assume that optometrists and registrants of the RDO Program are the same profession, resulting in confusion as to which agency a complaint should be submitted.

What may lead to further confusion is that current law does not allow optometrists and RDO registrants to have commingling business relationships. BPC § 655 provides that an optometrist shall not have any membership, proprietary, interest, co-ownership, landlord-tenant relationship, or any, profit-sharing arrangement in any form, directly or indirectly, with an RDO registrant and vice versa.

There have been lengthy legal battles regarding the validity of B&P Section 655; both the California State and United States Federal courts have made it clear that California law prohibits certain relationships between optometrists and RDO registrants and that these laws are valid and constitutional. The most recent ruling came from the United States Court of Appeals for the Ninth Circuit on June 13, 2012. The ruling affirmed the decision of April 2010 by a U.S. District Judge that the state acted well within its rights to prohibit these types of relationships. The Plaintiffs-Appellants, National Association of Optometrists & Opticians, LensCrafters, Inc., and Eye Care Centers of America, Inc., could seek review by an enlarged circuit panel or at the Supreme Court.

AB 778 (Atkins, 2011) would have authorized a registered dispensing optician, an optical company, a manufacturer or distributor of optical goods, or a non-optometric corporation to own a specialized health care service plan that provides or arranges for the provision of vision care services. It would have also allowed shared profits with the specialized health care service plan, contract for specified business services with the specialized health care service plan, and jointly advertise vision care services with the specialized health care service plan. This bill eventually died in the Senate Business, Professions and Economic Development Committee.

MBC has suggested that moving the RDO Program to the SBO might lead to more efficient investigation of complaints by eliminating the need for two agencies to investigate the same complaint when it involved an optometrist and an RDO Program registrant. The MBC has also suggested as another option to transfer the RDO Program to the Department of Consumer Affairs as a program or bureau.

Committee staff points out that The RDO Program has budget authority for one position to perform the Program functions. If the RDO Program were moved into its own program or bureau, it would no doubt demand more staff and thus, ultimately escalate costs and registration fees.

Staff does note, however, that there has been success over the last 20 years or more of combining related regulatory issues into a single board. Of particular note are the following:

- Combining of cosmetology regulation with barbering regulation into the Board of Barbering and Cosmetology.
- Combined regulation of the funeral home industry and the cemetery industry by the Cemetery and Funeral Bureau.

- Combined regulation of architects and landscape architects by the California Board of Architecture.
- Combined regulation of land surveyors, professionals engineers, geologists and geophysics by the Board for Professional Engineers, Land Surveyors and Geologists.
- Combined regulation of the electronic and appliance repair industry and the home furnishing and thermal insulation industry into the Bureau of Home Furnishings and Thermal Insulation, Electronic and Appliance Repair.
- Combined regulation of speech-language pathology and audiology along with the hearing aid dispenser regulation in the Speech-Language Pathology, Audiology and Hearing Aid Dispensers Board.

Although, practitioners have at times recoiled at the prospect of such combined regulation and fought against it, the successful combinations of related regulatory programs shown above demonstrate the reality that related professions may be successfully regulated together.

Staff Recommendation: Recommend the MBC to initiate discussions with the Department of Consumer Affairs, the State Board of Optometry, stakeholders from each of the interested professional groups, and interested consumer representatives to discuss the potential need, usefulness, or problems with transferring regulation of the RDO Program from the MBC to another board or program. The MBC should report its findings and recommendations back to the Committee by July 1, 2014.

#### MBC Response (April 2013):

The MBC will initiate discussions with the Department of Consumer Affairs, the State Board of Optometry, stakeholders from each of the interested professional groups, and interested consumer representatives to discuss the potential need, usefulness, or problems with transferring regulation of the RDO Program from the MBC to another board or program. The MBC will report its findings and recommendations back to the Committee by July 1, 2014.

## <u>ISSUE #38</u>: Consolidate the licensing and regulation of osteopathic physicians and surgeons under the MBC.

<u>Background</u>: Since the initiative establishing the Osteopathic Act and the Osteopathic Medical Board of California (OMBC) in 1922, California's public policy has been clear that osteopathic physicians and surgeons (DOs) are to be treated equally with physicians and surgeons (MDs) licensed under the MBC. BPC § 2453(a) states: "It is the policy of this state that holders of MD degrees and DO degrees shall be accorded equal professional status and privileges as licensed physicians and surgeons."

Moreover, this equality is so firmly established that it extends to a statutorily mandated rule of non-discrimination. BPC § 2453(b) states:

Notwithstanding any other provision of law, no health facility subject to licensure under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, no health care service plan, nonprofit hospital service plan, policy of disability insurance, self-insured employer welfare benefit plan, and no agency of the state or of any city, county, city and county, district, or other political

subdivision of the state shall discriminate with respect to employment, staff privileges, or the provision of, or contracts for, professional services against a licensed physician and surgeon on the basis of whether the physician and surgeon holds an MD or DO degree.

This equality, as well as the vastly coextensive education and training of MDs and DOs, and the exact parity of their unrestricted licenses and scopes of practice, raise a perennial question: Is there a continual need to have two separate regulatory bodies for these virtually identical professions? The question is particularly timely in light of the Governor's well-publicized desire to eliminate redundancies and inefficiencies in state government, and particularly in the structure of the state's boards and commissions.

The primary difference between DOs and MDs appears to be essentially one of emphasis. According to the Osteopathic Board, DOs have a different philosophy of medicine, focused on the interrelationship of the body's systems, a focus MDs do not share. Aside from that, both professions apparently have identical licenses, identical scopes of practice, and must be treated by insurers, hospitals, and government entities identically. They are held to apparently virtually identical standards of practice by hospital Peer Review Organizations and liability insurers, and, both the Osteopathic Board and the MBC use the same prosecutors when their licensees are subject to formal accusations. MBC already conducts all investigations and HQE conducts all prosecutions for the Osteopathic Board. OMBC simply has too few licensees to support a separate enforcement program — at least one of the physicians highlighted in the *LA Times* series (Dr. Lisa Tseng) is an osteopath, and it took the OMBC many years to suspend her license.

Is there a continuing need for two separate boards to regulate those who hold unrestricted licenses as physicians and surgeons?

If DO regulation were transferred to the MBC, it would appear appropriate to include osteopathic physician membership on the MBC.

<u>Staff Recommendation</u>: The MBC should discuss with the Committee the possibility of consolidating the OMBC into the MBC to provide a single regulatory authority over all physicians and surgeons in California.

#### MBC Response (April 2013):

The Senate B&P Committee background paper has asked if there is a continued need to have two separate regulatory bodies for these virtually identical professions, especially in light of the fact that OMBC has too few licensees to support a separate enforcement program.

This is not an issue that the MBC has fully discussed or taken action to approve or disapprove. The MBC agrees that the Committee(s) should take the lead on this issue and possibly hold an informational hearing on the subject of this potential consolidation of the MBC and the OMBC. In the meantime, staff can take this issue back to the MBC for a fuller discussion and direction to staff, so the MBC could fully participate in any consolidation effort led by the Committee.

<u>ISSUE #39</u>: (CONTINUED REGULATION BY THE BOARD.) Should the licensing and regulation of physicians and surgeons be continued and be regulated by the current Board membership?

**Background:** The public interest is best protected by the presence of a strong licensing and regulatory board with oversight over physicians and surgeons and the associated allied professions. Since the inception of MICRA in 1975, a strong and vigorous enforcement agency has been demanded in order to represent the interests of patients, their families and the people of California.

The MBC faces considerable challenges to being the consumer protection agency that is needed in the coming years. Sharp criticism has been levied against the board in recent years. However, the MBC has faced a number of challenges in seeking to fulfill its consumer protection mission: Budget crises, budget restrictions, hiring freezes, vacancies, staff furloughs have all contributed to limiting the Board's operations. However the Board needs be proactive in its approach; finding new ways to use technology to accomplish its consumer protection purposes.

The MBC should be continued with a 4-year extension of its sunset date so that the Legislature may once again review whether the issues and recommendations in this Background Paper have been addressed.

<u>Staff Recommendation</u>: Recommend that the licensing and regulation of physicians and surgeons and allied health professions continue to be regulated by the current board members of the Medical Board of California in order to protect the interests of the public and be reviewed once again in four years.

#### MBC Response (April 2013):

The Board appreciates the opportunity of the Sunset Review process and looks forward to working with both the Senate and the Assembly B&P Committees and their staff on issues that have been identified for future consideration. The MBC is pleased that Committee staff has recommended that the licensing and regulation of physicians and surgeons and allied health professions continue to be regulated by the current Board Members of the Medical Board of California in order to protect the interests of the public and be reviewed once again in four years.