MEDICAL BOARD
OF CALIFORNIA
Protecting consumers by advancing high quality, safe medical care.

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Gavin Newsom, Governor, State of California | Business, Consumer Services and Housing Agency | Department of Consumer Affairs

Crowne Plaza San Jose–Silicon Valley
777 Bellew Drive
Milpitas, CA 95035
January 31 – February 1, 2019

MEETING MINUTES

Thursday, January 31, 2019

Due to timing for invited guests to provide their presentations, the agenda items below are listed in the order they were presented.

Members Present:
Denise Pines, President
Michelle Anne Bholat, M.D., Secretary
Susan F. Friedman
Dev GnanaDev, M.D.
Randy W. Hawkins, M.D.
Howard R. Krauss, M.D.
Ronald H. Lewis, M.D., Vice President
Laurie Rose Lubiano, J.D.
Brenda Sutton-Wills, J.D.
David Warmoth
Jamie Wright, J.D.
Felix C. Yip, M.D.

Members Absent:
Kristina D. Lawson, J.D.

Staff Present:
April Alameda, Chief of Licensing
Erika Calderon, Staff Services Manager I
Mary Kathryn Cruz Jones, Associate Governmental Program Analyst
Christina Delp, Chief of Enforcement
Kimberly Kirchmeyer, Executive Director
Christine Lally, Deputy Director
Victoria Ornduff, Information Technology Technician
Regina Rao, Associate Governmental Program Analyst
Letitia Robinson, Research Data Specialist II
Elizabeth Rojas, Staff Services Analyst
Jennifer Simoes, Chief of Legislation
Kevin Valone, Staff Services Analyst
Carlos Villatoro, Public Information Manager
Kerrie Webb, Staff Counsel

Members of the Audience:
Eric Andrist, Patient Safety League
Gloria Castro, Senior Assistant Attorney General, Health Quality Enforcement Section, Attorney General's Office
Yvonne Choong, California Medical Association
Phillip Coffin, M.D., San Francisco Department of Public Health
Zennie Coughlin, Kaiser Permanente
Robert de los Reyes, Budget Manager, Department of Consumer Affairs
Connor Finney, Consumer Watchdog
Kanwar Gill, M.D.
Kara Hallsten, Investigator, Health Quality Investigation Unit, Department of Consumer Affairs
Marian Hollingsworth, Patient Safety League and Patient Safety Action Network
Todd Iriyama, Supervising Investigator, Health Quality Investigation Unit, Department of Consumer Affairs
David Kan, M.D., California Society of Addiction Medicine
Wendy Knecht
Susan Lauren, Lipo Coalition
Patrick Le, Assistant Deputy Director, Board and Bureau Services, Department of Consumer Affairs
Edward Machtinger, M.D., University of California, San Francisco
Paul Marchand, M.D.
Lisa Matsubara, California Medical Association
Michelle Metcalf, Investigator, Health Quality Investigation Unit, Department of Consumer Affairs
Michelle Monseratt-Ramos, Consumers Union Safe Patient Project
Kathleen Nicholls, Deputy Chief, Health Quality Investigation Unit, Department of Consumer Affairs
James Nuovo, M.D., University of California, Davis
Kerry Parker, California Society of Addiction Medicine
Katie Rodriguez, California Healthcare Foundation
Hanna Rhee, M.D., Black Patients Matter
Mike Sanchez, Videographer, Department of Consumer Affairs
Mark Scarlett, Supervising Investigator, Health Quality Investigation Unit, Department of Consumer Affairs
Taylor Schick, Budget Officer, Department of Consumer Affairs
Jaimee Tassio, Investigator, Health Quality Investigation Unit, Department of Consumer Affairs

Agenda Item 1 Call to Order/Roll Call/Establishment of Quorum

Ms. Pines called the meeting of the Medical Board of California (Board) to order on January 31, 2019 at 2:48 p.m. A quorum was present and due notice was provided to all interested parties.

Agenda Item 2 Public Comments on Items not on the Agenda

Dr. Coffin Director of substance use research at the San Francisco Department of Public Health, reported that through the trainings he has heard that there are many prescribers throughout the state that have stopped prescribing opioids due to fear of the Board's death certificate project. He provided more insight into these fears and explained the effects they are having on the prescribers and consumers. He shared findings from a study funded by the Centers for Disease Control and Prevention (CDC), and noted specific effects on his local community. He stated that physicians are not willing to treat with buprenorphine out of fear of Board action. Dr. Coffin concluded by urging the Board to discontinue the project since it is unintentionally harming patients.

Dr. Kan, President of the California Society of Addiction Medicine (CSAM), gave details about his organization and shared that he was there speaking on behalf of their members and their patients. He noted that the death certificate project has had adverse outcomes on patients and for this reason he recommended that the Board halt the investigation process. He provided more insight into the basis of his recommendation and provided evidence from a CSAM survey. He added insight that he has gained from other physician groups that also have vocalized concerns for their patients and physicians' fear of over prescribing. Dr. Kan stated the project is forcing physicians to perform involuntary patient tapering. Dr. Kan wrapped up by asking the Board to suspend all investigations until the exact impact of the CDC guidelines is known and necessary amendments to the project can be made.

Dr. Machtinger, Professor of medicine at the University of California, San Francisco and Director of the women's HIV program, urged the Board to pause the death certificate project since the impacts are unintentionally harming patients. He clarified why the project is posing a problem in the healthcare community. He pointed out that there is a lack of detailed guidance by the Board to ensure a provider is in full compliance when treating these complex patients. He shared that the patients that are being adversely affected by the project are predominantly African American, Latino, or are from other minority groups. He highlighted the racial disparity and provided more information about implicit bias in the medical community. Dr. Machtinger advocated for California's minority populations by asking that the Board pause the death certificate project and retailor it to improve it.

Mr. Andrist, Patient Safety League, stated he supports the death certificate project and shared his personal story of loss, his complaint with the Board against a doctor whose actions led to the loss of his sister, and updates to this complaint with the Board of Registered Nursing. He welcomed the two new Board Members and discussed the loss that the Board has experienced with the resignation of Judge Feinstein. He reminded the Board of their responsibility to protect consumers against bad doctors and part of that includes taking an active interest in what consumers and advocates want to share with the Board. Mr. Andrist concluded by sharing that he emails Board Members with updates

about his organization's investigations about the Board and asked that Board Members respond out of professional courtesy since the information is pertinent to their role as a Member.

Dr. Rhee, member of the California Medical Association (CMA), outlined concerns and provided some solutions for problems that she encounters as an outpatient, non-hospital affiliated physician working with Medicare patients. She added that she has heard from many patients that they feel that doctor's office staff does not care about them and she noted that doctor's office staff needs to diversify. She requested that Black Patients Matter be given the opportunity to present on racial disparities. Dr. Rhee concluded by calling upon the Board to stop contracting with medical experts that lack training in racial and religious diversity and asked that the Department of Consumer Affair's (DCA), Division of Investigation diversify.

Ms. Lauren, Lipo Coalition, indicated ways in which she believes the Board is failing and provided details of her personal story and closed complaint with the Board. She added that medical harm is covered up by the Board, which she stated is unacceptable. She explained the medical assault that happened to her and how criminal cover-up defines her case. She noted that law enforcement has expressed interest in wanting to investigate her case, however, their hands are tied since it is under the justification of the Board. She shared how she was discriminated against by the Board by denying telephone access for the patient advocate meeting that was scheduled earlier in the month. Ms. Lauren concluded by asking for an audit of the expert reviewer that was a part of her case.

Dr. Gill provided an explanation as to why he feels that the death certificate project is misguided, timed improperly, and does not take into consideration the full spectrum of the problem. Speaking to the timeline, he recalled that the Board took action on this project in January 2017, however, action should have been taken back in 2013. He proposed that the project is related to the outcome of the 2016 November election and he provided more reason for his rationale. He continued to explain the origins of the opioid crisis and emphasized that it is a white middle-class problem that needs addressing. Dr. Gill concluded by noting that the first thing that needs to be addressed is dealing with patients that cannot obtain their prescriptions since their doctor is afraid of prescribing.

Agenda Item 3 Approval of Minutes from the October 18–19, 2018, Quarterly Board Meeting and December 18, 2019 Board Meeting

Dr. Lewis made a motion to approve the October 18-19, 2019 meeting minutes; s/Dr. Krauss. Motion carried (11-0-1, Friedman abstained).

Ms. Wright made a motion to approve the December 18, 2019 meeting minutes; s/Dr. Lewis. Motion carried (9-0-3, Friedman, Krauss, and Lubiano abstained).

Agenda Item 4 President's Report, including notable accomplishments and priorities

Ms. Pines introduced and welcomed the two new Board Members, Ms. Friedman and Ms. Lubiano, and provided some background information about them prior to swearing them in as Members. She announced Dr. Levine's resignation from the Board and thanked her for her service.

Ms. Pines noted that she and Dr. Lewis had calls with executive staff to discuss the meeting agenda and other Board projects. She provided updates about the Board including the release of the Annual Report, a new podcast, and the President's award, which was given to Mr. Eslami and Mr. Eichelkraut for the development of the iOS application. She disclosed that in addition to a call with the DCA regarding the budget she also met with the CMA Executive Committee to discuss goals and plans for the Board. Ms. Pines concluded by noting new changes to Board Committees and Panels.

Ms. Andrist inquired about the overall usage of the application by consumers in addition to the feedback received about the application.

Agenda Item 5 Board Member Communications with Interested Parties

Dr. GnanaDev noted that he had received many calls regarding the new law regarding prescription pads and the short timeframe given to comply as well as many questions regarding the death certificate project.

Mr. Finney, Consumer Watchdog, applauded the Board for improving communication with California's patients and patient advocates and urged the Board to continue to conduct interested party meetings regularly. He added that he hopes that the Board will continue with the death certificate project and provided reasons as to how this project protects the California patient population.

Mr. Andrist inquired if Ms. Wright would like to disclose that she spoke with Mr. Johnson during the last Board Meeting. He then asked what other communications happened but are not divulged. He commented that he filed a complaint against Ms. Wright and requested that it be taken seriously.

Agenda Item 6 Executive Management Reports

Ms. Kirchmeyer noted that the Board has one budget change proposal to increase the hourly rate of the medical experts as was requested by the Board and listed in the Board's Strategic Plan. She added that there are three proposals that will impact the Board including an increase in funding for medical consultant hours at the Health Quality Investigation Unit (HQIU) at DCA to aid in investigations, a decrease funding for the Attorney General (AG's) Office due to the elimination of vertical enforcement (VE), and an increase in staffing at DCA to assist in the regulation review, fiscal operations, business services, and personnel. She highlighted the effect of these proposals and reminded the Board it may need a fee increase if current spending remains the same.

Ms. Kirchmeyer provided updates on Board projects, specifically the postgraduate training requirements and the Licensed Physician and Dentists Mexico Pilot Program. She explained the outreach that has been provided regarding the new licensing requirements, including holding future webinars and a dedicated webpage. She also stated that staff are completing applications for the Mexico Pilot Program so the physicians will be able to apply for the special license.

Ms. Kirchmeyer discussed the creation and implementation of the death certificate project. She explained how the Board entered into an interagency agreement with the California Department of Public Health (CDPH), to receive death certificates related to opioids. She provided the process for

this project and how the Board identified physicians who may be inappropriately prescribing. Ms. Kirchmeyer provided insight into the enforcement process and provided statistics about the project, demonstrating the importance of the work. She concluded by noting that the physician experts did appropriately complete their initial review in identifying physicians with potential prescribing issues. She added that staff would be making some changes in the methodology to improve the project. She stated that the expert reviewers will be reviewing the physician's complete prescribing practices, not just the deceased patient, and will also be looking at the deaths from years 2016 and 2017.

Ms. Kirchmeyer gave updates on some of the Board's task forces. She pointed out that the Prescribing Task Force may be meeting to determine if any changes need to be made to the Guidelines for Prescribing Controlled Substances for Pain, such as a section regarding care and treatment for patients that may be addicted or on high doses of opioids. She added that over the next quarter there are plans for the Stem Cell and Regenerative Therapy Task Force to meet to discuss the Federation of State Medical Board's policy and recommendations.

Ms. Kirchmeyer gave an update on the Physician Assistant Board (PAB) starting with the election of Mr. Grant to PAB president and Mr. Sachs to vice president. She provided an update of PAB programs and number of graduates nationwide and compared that with the programs in California. Additionally, she discussed approved regulations by the PAB, giving focus to the initiation of the rulemaking proposals to implement Assembly Bill (AB) 2138, which also affects the Board.

Dr. Yip inquired if a memo or update could be provided to the website to inform the public about the effects of the death certificate project. He also inquired more about the increase and the decrease of the budget to make it the most effective for the Board.

Ms. Kirchmeyer explained that even though HQIU is under DCA the budget increase still needs to be approved by the Board, since it will impact the Board's budget. She added that although the Board does not pay HQUI an hourly rate, the Board pays a yearly amount and then HQIU determines how to best spend the money. She contrasted this with the AG's Office, which is paid an hourly rate and has a defined amount due to VE. She explained that with the cancellation of VE, the Board is now recovering those funds.

Dr. Hawkins asked for more information about the Prescribing Task Force.

Ms. Kirchmeyer answered that currently only Ms. Lawson is serving on that Task Force, but changes to the Members will happen in the future.

Dr. Bholat asked if the death certificate project data is broken down by specialty, and if not she recommended that it is since approaches differ depending on specialty. She noted that this could also be helpful to understand the current state of pain management. She concluded by asking other than the guidelines if there are other modalities that could help inform physicians and protect consumers.

Ms. Kirchmeyer responded that the Board is currently looking into understanding how to find a way to get physicians to read the information put out by the Board, such as the Prescribing Guidelines. She provided insight into her experience providing presentations throughout the state and shared an example of a large health group in California that has taken this issue very seriously and changed their electronic health records to help physicians, created programs with non-pharmaceutical treatments, and provided training to their staff about medication-assisted treatment and buprenorphine. She concluded that this organization's response to the opioid epidemic is far different from anything that she had experienced. She also pointed out that there are still a lot of physicians that are completely unaware of the Prescribing Guidelines.

Dr. Lewis inquired if region would also be a contributing factor.

Dr. Bholat agreed with him and added that education is a large piece of this as well. She added that instead of physicians being fearful, they should be partnering to understand how to best treat consumers.

Dr. GnanaDev provided some insight into the increased deaths from illegal opioids, specifically fentanyl, and the potency of these illegal products. He said it is important that the doctors are not scared, however, it is important for the Board to enforce the law when a physician is inappropriately prescribing. He confirmed that the project will continue to evolve, for example, the Board has already modified the letter sent to physicians to inform them that a case is being opened. He concluded that the focus of the project is to identify the chronic inappropriate prescribers and that now the issue is addiction management.

Dr. Bholat reiterated that education is a large part of this and provided information into tapering. She urged the Board to look into the X waiver and buprenorphine. She added this would provide more access for people to have treatment.

Dr. Yip spoke to his own experience about CMEs and the prescribing guidelines. He echoed the importance of education in the community and noted that the reality is that more physicians need to be educated. He recommended that the Prescribing Task Force take this into consideration and maybe even require educational courses so that physicians can be more knowledgeable.

Ms. Kirchmeyer added that there is a provision that would allow an individual to count the training in medical school as meeting the training hours for the X waiver if the curriculum meets the requirements. She added that the Board is working with an organization to obtain more information about this provision and that it would not be possible without the authorization of the Board.

Dr. Rhee, member of CMA and Black Patient's Matter, shared that she has a problem with funds going to HQIU and DCA since they are not diversified organizations. Her reasoning for this was that with the lack of a diversified workforce, there will be investigative bias. She noted that there is concern of DCA's hiring practices and recognizing underrepresented minorities.

Mr. Andrist commented that the Board is only disciplining four percent of the complaints received, he then asked if the Board only budgets to handle four percent. He shared that some of the worst physicians he has entered in his database studied in Mexico and proceeded to provide examples of these doctors with disciplinary action. He asked for total costs for attorneys to defend the Board from non-enforcement lawsuits from the public and disgruntled doctors. He noted that he submitted a Public Records Act request with regard to Board Member expenses for 2015. Mr. Andrist shared some numbers from Board Member expenses and questioned the totals.

Agenda Item 7 Update on the Budget and Revenue

Mr. Schick, DCA Budget Officer, introduced Mr. De los Reyes, DCA Budget Manager, who gave an update and some background on Fi$Cal, which is the new system being used by the State to track revenue and expenditures. He shared that currently reports are lacking information and are not ready for dissemination. He noted that the department has yet to close final fiscal statements for 2017-18, but they are expected to be closed in March 2019. He shared that they work with boards on a monthly and quarterly basis to get all the information to prepare expenditure and revenue projections, as needed.

Mr. Schick transitioned to the fund condition and he noted that there is a structural imbalance with the Board. He clarified that this means that the revenues are less than the expenditures. He confirmed that there is a need for a fee audit to look at how the fees need to be restructured to support the Board going forward. He provided context as to what a fee increase means, what the fee was previously, and other costs that have increased since the last time fees were raised. Mr. Schick stated the fund has a statutory provision that it must be within two or four months in reserve. He commented that the Board is projected to drop below the two-month reserve and therefore action is needed. He recommended that the Board conduct an independent fee audit to try and realign the fees as appropriate to support the fund and the Board’s operation.

Ms. Pines inquired if the Board would pay for the audit or DCA.

Mr. Schick responded that traditionally the boards pay for this. He noted that an independent audit is best since it will be the basis for the Board's decision-making process to set fees and will affect the legislative bill that is written to request the increase.

Dr. GnanaDev asked if all the money in the fund is from license fees.

Mr. Schick confirmed that there is no general fund money in the fund.

Dr. GnanaDev asked if the audit is done only on the revenue or on the expenses as well.

Mr. Schick answered that it will be a full review.

Dr. GnanaDev inquired if fees in other states are taken into consideration.

Mr. Schick verified that comparable states are a factor.

Dr. Yip pointed out that these numbers do not reflect the current vacancies. He noted that if the Board is fully employed, there is less money to spend.

Mr. Schick stated the fund condition assumes that the budget is fully expended, however not all the funds may be used. He reiterated that there is an expectation that the Board will be very close to expending the full budget this year.

Dr. Yip inquired about previous loans.

Mr. Schick confirmed that all outstanding loans were repaid. He stated the fee increase needs to go to the Legislature since the Board is at the fee increase cap.

Mr. Andrist vocalized his thoughts about BreEZe and noted that more money was spent on BreEze than originally anticipated. He recommended that the Board investigate other technologies, since it is not the most effective tool for consumers.

Agenda Item 8 Presentation on Expert Reviewer's Role in the Enforcement Process

Ms. Kirchmeyer noted that there are three physician roles within the Board's enforcement process, specifically the Central Complaint Unit reviewers, the district medical consultants, and the expert reviewers.

Dr. Nuovo provided some background and began explaining the requirements to be an expert reviewer, provided information about the expert reviewer training program, and discussed the guidelines that the expert reviewers need to follow. He shared that it is paramount for a reviewer to remember that every case is unique and deserves to have all the information reviewed thoroughly, and to have an opinion provided. He shared that a key role is to educate and explain why they came up with their opinion. He provided information about the role of the reviewer in the Central Complaint Unit and highlighted the goals as a reviewer. Dr. Nuovo emphasized that they provide an independent review and noted the importance of ensuring there is no conflict of interest. He discussed the review process, writing reports, and common themes for the violations found. Dr. Nuovo concluded that the main role of the reviewer is to provide independent, impartial, and unbiased conclusions.

Ms. Wright questioned how in some reviews she sees that the expert opinion is not in the same specialty as the accused physician.

Dr. Nuovo pointed out that there may be overlap of areas that would allow an expert in a different field to opine. He remarked that there is crossover within specialties within some complaints. He reinforced that it must be based on the event that occurred and using best judgment as to who is best expert for the case.

Ms. Wright inquired who makes that decision.

Dr. Nuovo noted that it depends on whomever is the most qualified to opine on the case.

Dr. Hawkins mentioned that some expert reviewers provide good information that enables the Board Members to come to a decision, however it is not uncommon to see an expert reviewer change their mind about their opinion during the case process. As a result, the legal team worries that the expert reviewer changing their stance will affect the chances of winning the case should it go to hearing. He asked what could assist the expert reviewers to ensure their opinion holds up in court.

Dr. Nuovo explained that there could be a variety of circumstances, including new or additional information that is provided to the expert reviewer that changes the facts of the case. In addition, it is important that there is a quality assessment of the reviewers. He explained that some reviewers follow the recommendations and the training, whereas for others, it is important to provide additional training and ensure they understand the requirements for reviews. He pointed out that in some instances the Board may not use the reviewer in the future.

Dr. Bholat inquired how designated institutional officials (DIO) and program directors can be educated on topics such as negligence, competence, lack of knowledge, excessive prescribing, and unprofessional conduct.

Dr. Nuovo provided some insight into his background as residency director, dean, and DIO and shared that this is a challenging area. He clarified that that the governing body for residency training is the Accreditation Council for Graduate Medical Education (ACGME) who sets rules, regulations, and guidelines on how to assess the competence of every resident. He noted that the goal of the residency director is ensuring the physician in training is competent and capable of practicing independently without direct supervision, however this is not always the case. Dr. Nuovo pointed out that there have been studies that problematic medical students become problematic residents, which become problematic licensees. He wrapped up by noting that the work done by the Board is critical.

Dr. Yip asked for statistics about the specialties of experts and inquired if there are random reviews of the quality of medical reviewers' work.

Ms. Kirchmeyer reminded the Board that there are two different types of reviewers. She clarified that there are medical consultants that work with the Central Complaint Unit and their work is reviewed by the managers. She noted that there is education to assist with writing, style, and format. She mentioned that there are also expert reviewers that work with HQIU. Ms. Kirchmeyer shared that feedback given from the investigators and Deputy Attorneys General goes into the expert reviewer database. She explained that for the experts that work the with AG's Office, they receive a written evaluation.

Ms. Kirchmeyer stated that in reference to Dr. Hawkins' question, opinions are changed most often due to information received during the discovery process. She noted that when information is provided from defense counsel, it is provided to the expert for review and this sometimes changes the

expert's opinion. She explained in reference to Dr. Yip's question that the caseload of a reviewer is in constant rotation and the Board does ensure that the specialties are matched.

Dr. Lewis asked for further clarification about consultants versus reviewers.

Ms. Kirchmeyer explained the process begins with the upfront reviewers, also called medical consultants. This is then followed by the district medical consultants, who are in the field and are employees of HQIU. The last reviewers are the expert reviewers that make the final review and decision if there is a departure from the standard of care.

Dr. Krauss noted that there are about 10,000 complaints per year and suggested that not all complaints are due to physician misconduct. He inquired what percentage of complaints appropriately lead to a request for a physician's record, which launches some level of investigation.

Dr. Nuovo confirmed that some complaints that come through are not related to the physician but could be related to coverage issues. He continued that those complaints are triaged out appropriately.

Ms. Kirchmeyer shared that of the 10,888 complaints from the last fiscal year, 4,956 were considered gross negligence or incompetence. She specified that there were 200 in fraud, 800 in health and safety, and 1,200 non-jurisdictional complaints. She added that there were 450 personal conduct, 2,900 unprofessional conduct, and 400 unlicensed complaints.

Dr. Rhee commented that doctors need to recognize and acknowledge that there will always be some sort of bias. She noted that Dr. Nuovo mentioned there is no bias, but she remarked that is not true. She shared that in her own case the expert reviewer did not have any specific education or background training in racial or religious diversity. She emphasized the importance of this training and that the lack of it could result in a bias.

Ms. Hollingsworth, Patient Safety League and the Patient Safety Action Network, expressed her concern for conflicts of interest within the expert review program. She provided an example of a doctor from Inland Empire that was arrested and convicted of drunk driving. She shared that he was evaluated by a physician that is a close family friend and this same physician testified on his behalf. Ms. Hollingsworth indicated that instead of receiving five years of probation, as recommended for discipline under the Board's guidelines, the doctor got a reprimand with no routine testing for alcohol or any educational classes. She questioned how this was not a conflict of interest, how it was allowed, and how often it happens.

Mr. Andrist wondered whether that Dr. Nuovo was the expert that reviewed the case for his sister and found it ironic that he stressed the importance of all the materials needing to be reviewed when in the case of his sister there was not a copy of her certified medical records before the case was closed. He questioned what the expert was doing in this case. He shared that the consumer may turn in a complaint without understanding the process or may be under the impression that there will be an in-depth interview. Mr. Andrist remarked that the Board often refuses to interview a complainant and he

provided his personal story. He highlighted the fact that in the case of his sister it was halted by the expert reviewer without all the information of the case and when he requested information about the reviewer he received none. He explained that his request for more information was to decipher if the expert was qualified or had a conflict of interest with the case. He concluded by stating that the process is not transparent and does not encourage patient safety.

Agenda Item 9 Discussion on Possible Action on Legislation/Regulations

Ms. Simoes explained that the 2019 legislative session started and 2019 is the first year of a two-year session. She updated the Board on the 2019 Legislative Day, noting that it will be in April or May. She reminded the Board that at the last Board meeting three proposals were approved, the first being to amend and Business and Professions (B&P) Code section 800(c), striking the word comprehensive in front of summary, since it can delay and impede the physician interview and investigation. The second was to require probationary license information to stay on the Board's website after probation was completed for a period of ten years. Ms. Simoes shared that the third was to amend B&P Code section 2234(h), regarding physician interviews, to strike the word to strike the word repeated, which would mean that if a physician failed to attend one time it would qualify as unprofessional conduct. She noted it would be best to put all three proposals into one bill and Board staff are trying to secure an author to carry all three amendments.

Ms. Simoes introduced Assembly Bill (AB) 149, Cooper. She reminded the Board of AB 1753, Lowe, which became effective January 1, 2019, and required that all prescription forms include a uniquely serialized number in a manner prescribed by the Department of Justice (DOJ), however the bill did not include a transition period to allow time for prescribers to order the new prescription forms. She explained the change resulted in many prescribers ordering forms right before it took effect and thus caused difficulties for patients trying to get their prescriptions. She explained that AB 149 is providing a transition period for the implementation of this requirement and specifies that a prescription for a controlled substance written on an otherwise valid prescription form prior to January 1, 2019, is a valid prescription and may be filled, compounded, or dispensed until January 1, 2021. Ms. Simoes added that if DOJ determines that there is an inadequate availability of compliant prescription forms to meet the demand, the transition period can be extended an additional six months. She shared that the bill includes an urgency clause, meaning that it becomes effective when the Governor signs it. She noted that the Board has been receiving numerous calls and emails daily from prescribers and patients regarding the difficulty of obtaining the new prescription forms and this bill will help to ensure that patients receive their medications in a timely manner. For this reason, Board staff recommends that the Board take a support position.

Dr. GnanaDev remarked that he received numerous calls regarding this bill. He provided information about his own clinic and how they had issues with the transition.

Ms. Simoes confirmed that she received many phone calls from confused physicians or physicians wondering why they needed to purchase new prescription pads.

Dr. Lewis pointed out that there are only three printers that print the pads.

Ms. Simoes noted that there are actually more. She added that DOJ has authority over security printers, but information regarding security printers was given out through one of the two notices that the Board disseminated. She noted that on the notice it has the information for DOJ.

Dr. Hawkins noted that there may be many physicians who are upset by this law. He shared that he threw away his old prescription pads, bought new ones, and now to know that he could have used what he threw out is not reassuring.

Ms. Simoes answered that when she receives phone calls from physicians, she recommends that they do not throw out their prescription pads since this new bill is pending.

Dr. Krauss made a motion to support AB 149; s/Dr. Lewis.

Ms. Friedman inquired how much prescription pads cost. She asked why this was not done within six months instead of a year since the issue of opioids is so urgent.

Ms. Simoes answered that many others have that same question. She confirmed that there should be some time allotted for a transition and this should have been accounted for in the original bill.

Dr. Hawkins noted that his pads cost over $300 and he had enough pads in his inventory to last over a year but had to throw them away due to AB 1753.

Dr. GnanaDev stated that the law had good intent, but unfortunately DOJ did not have solutions, so it will have to go through the legislature again.

Ms. Hollingsworth, a patient safety advocate, inquired about an update on a bill proposal regarding doctor interviews and including a timeline for physicians to be interviewed as discussed at the July 2018 Board meeting.

Ms. Simoes responded that at the October meeting the Board did not approve making the interview required within a certain timeline. She noted that if an author were to introduce a bill, she would bring it back before the Board for approval. She reiterated that she is having difficulties securing an author for the changes that were approved.

Ms. Hollingsworth responded that she was hoping for some reasonable agreed upon time limits. She updated that Senate Bill (SB) 1448, A Patient's Right to Know Act, has been introduced in Washington, thanks to the example of California.

Motion carried (11-1, Hawkins).

Ms. Simoes provided an update on the approved post graduate training regulations which were approved by DCA on January 14, 2019. She explained that due to the timing of when the regulation was approved, it did not allow staff enough time to provide notice to hold the hearing during the Board

meeting. For this reason, the regulations hearing will be held separately prior to the May Board meeting.

Agenda Item 10 Discussion on Passible Action on the Brochure "Therapy Never Includes Sexual behavior"

Ms. Kirchmeyer explained that this brochure is required pursuant to B&P Code section 337 and 728. She noted that over a year ago the Board of Psychology began revising the brochure to make it more relevant. She shared that although most of the changes have already been approved, due to the passage of AB 2968 (Levine, Chapter 778), there are some revisions needed to the brochure. She added that the changes in color are the most recent changes and are quite minor. Ms. Kirchmeyer requested a motion to approve the brochure to allow for the printing and dissemination of the brochure to patients and providers who are required to provide the brochure.

Dr. Krauss made a motion to approve the amendments to the brochure; s/Ms. Wright.

Ms. Choong, CMA, recommended one minor change on page three, line 112, with regard to the description of who the booklet applies to, specifically physicians and surgeons. She noted that since physicians are not specifically licensed to practice psychiatry, it would be more accurate to list physicians and surgeons. She explained that to limit the confusion, it would be best to remove the word psychiatrist, since psychiatry is not separately licensed.

Ms. Kirchmeyer invited the Board Members to comment on this change, but explained that this was done for the public, as there seems to be some confusion as to who licenses psychiatrists. She noted the high number of calls made to the Board requesting this information. She explained that this correction was made to clarify that psychiatrists are physicians and surgeons.

Dr. GnanaDev recommended the use of the word including, to read as including psychiatrists.

Ms. Kirchmeyer confirmed that this is an appropriate edit.

Dr. GnanaDev added that without parens it looks odd and may raise more questions about who is a physician, surgeon, or a psychiatrist.

Ms. Kirchmeyer pointed out that it may even be clearer to add a sentence that says psychiatrists are physician and surgeons.

Mr. Warmoth added that given the material of the brochure, it is critical that it specifically mentions psychiatrists.

Ms. Pines asked how this brochure is to get out to physicians.

Ms. Kirchmeyer responded that there is a current brochure that is available, however once this brochure is updated, it will be tweeted, go in the newsletter, emailed to physicians, and sent out via a subscriber's alert. She added that once updated, the Board will be giving out this brochure as well.

Dr. Lewis recommended adding this to the outreach program.

Mr. Andrist noted that one-third of all doctors in California are members of CMA. He added that the majority do not belong to CMA and that CMA does not speak for all doctors.

Motion carried unanimously (12-0).

Agenda Item 11 Discussion on Possible Action on the Questions Pertaining to Impairment on the Applications for Licensure and Registration

Ms. Kirchmeyer reminded the Board that at the July meeting she provided information on several policies that were approved at the Federation of State Medical Boards (FSMB). She added that one policy was on physician wellness and burnout. She explained that FSMB recommends that boards review their applications to determine if appropriate questions are being asked regarding impairment pursuant to the Americans with Disability Act (ADA). Specifically, the focus of the questions should be on current impairment and not on illness, diagnosis, or previous treatment.

Ms. Kirchmeyer directed members to their packets and explained that Board staff provided two options to amend the current application questions for the Board's consideration. She explained that option one removes all open and unlimited questions and provides three questions. She elaborated that one question is related to any emotional, mental, physical, behavioral, or addictive disorder that would impair the applicant's ability to practice medicine safely. She detailed the second, which questions if the applicant has a neurological or other physical condition that would impair the applicant's ability to practice medicine safely. She listed the third question, which asks for any other condition that would impair or limit the applicant's ability to practice medicine safely. Ms. Kirchmeyer identified that the second option would be to remove all open and unlimited questions and to provide one question. She pointed out that the question is all-inclusive and just asks if the applicant has any condition that impairs the applicant's ability to practice medicine safely. She noted that this question does give examples of what that impairment may be. She concluded that Board staff recommends the use of the first option, since it allows applicants more options to be able to specifically identify what their potential impairment is.

Ms. Friedman vocalized that she did not feel that people would be honest when asked if they have a mental condition that would prevent them from practicing medicine safely. She recommended that the question ask if they have a mental condition, then provide space for an explanation, and then provide space for an explanation of how they deal with this in their practice. She noted that the current recommended form, she did not believe that anyone would answer truthfully.

Dr. Krauss agreed with Ms. Friedman and commented that he did not think that the Board needed to make the prospective changes in terms of violating the Americans with Disabilities Act. He

recommended that if the Board becomes required to not have an open-ended question or if legal action is taken to bar the Board from asking these questions, changes would need to be made. He added he does not agree with protecting the rights of the individual over the rights of consumers or constricting the Board, unless the Board was obligated to do so.

Ms. Kirchmeyer explained that some states have chosen to exclude these questions from either the initial application or the renewal application or from both. She confirmed that the Board should not remove the questions, especially on the initial application, but should consider amending them. She also noted that at this time there is no state mandate to change the questions, so the Board can choose how it would like to proceed.

Ms. Webb detailed that there has been action in other states regarding other licensees. She explained that there are some concerns in this area. She listed the first, which is that if people must disclose this information to get a license, they will not seek treatment where there can be documentation of it. Additionally, applicants are asked in the application about any issues they had in medical school or residency, as well as if they have had any action against a license they held in another state. She explained that this allows opportunities to discover if they have an impairment that would affect their ability to practice. Ms. Webb specified that if there are unusual circumstances, more information is gathered to understand the problem. She clarified that while there is no current action against the Board, she shared that it may be something that could happen in the future.

Dr. Lewis inquired if a current issue was the emphasis on the questions being asked.

Ms. Webb answered that it does ask about their current status, but information about their past would be obtained in asking about their medical school, residency, and other state actions.

Dr. Lewis asked for the source of this information.

Ms. Webb explained that it would be received from the medical school, the place of their residency, and other state medical boards.

Dr. Lewis expressed his uncertainty about this matter, especially for new applicants. He noted that he feels that people will be driven away and it would not serve to protect consumers.

Ms. Webb remarked that this is the reason why the questions are changing so that applicants would not have to report a condition that does not impair their ability to practice safety.

Dr. GnanaDev explained that these questions should help to take the stress off newer and younger applicants. He shared that the most stressful thing in any education is medical school and residency due to the amount of hours that they are working and studying. He commented that they do breakdown and deserve to get treatment through that time. Dr. GnanaDev confirmed that he is supportive of either option and that he likes the questions since they consider impairments and disabilities.

Dr. Krauss asked in the current format of the application, how many applications have indicated something regarding impairment that would not have been known or considered without these questions.

Ms. Kirchmeyer answered that unfortunately the senior staff review does not separate that information. She explained that the categories are alcohol and drugs, postgraduate or medical knowledge issues, convictions, and other. She continued to explain that the biggest issue with question one is that it is very open with no time limit, since it simply states anytime.

Dr. Lewis asked if a decision needed to be made that day.

Ms. Kirchmeyer clarified that the topic can be tabled. She noted that Board staff can also look into other entities' questions and gather more information.

Dr. Krauss made a motion to table the conversation, refer the matter to a committee to be appointed by the President in relation to physician wellness, and to report back for action; s/Dr. Lewis.

Ms. Choong, CMA, remarked that revising the questions related to impairment is intended to reduce the stigma around seeking treatment for medical needs. She added that both options are a significant improvement over the existing questions, however CMA believes that the second option would be better. She explained there could be coexisting conditions, which could be explained in one area, versus separating them out. She added that the broader question could allow for more space to explain the situation.

Motion carried unanimously (12-0).

Agenda Item 12 Update on the Strategic Plan

Ms. Robinson reminded the Board that the previous January they had adopted a new four-year strategic plan, which is guided by the Board's mission of consumer protection and organized by five goal areas, specifically licensing, enforcement, legislation and regulation, outreach, and Board administration. She noted that a large accomplishment of the Board was the launch of the license alert mobile app for Apple iSO devices, which allows consumers to follow and receive notifications about licenses. She explained that licensing is preparing for a new change due to the requirement for three years of post-graduate training, which will begin January 1, 2020. She detailed that licensing is working on revising applications and forms, hosting webinars, and making changes to the BreEZe system to prepare for the changes. Ms. Robinson shared that enforcement developed a real-time monitoring program to reduce case aging, a new case initiation process to reduce the time it takes to notify a complainant that their complaint was received, and implemented changes to the expert reviewer program to reduce costs. She noted that in terms of legislation and regulations, the Board had a successful Legislative Day with several legislators and reviewed the Board's laws and regulations to incorporate suggestions from stakeholders. She commented that there will be a webpage released later in the year to educate stakeholders on legislation of interest to the Board and

how the public can participate. She remarked that regarding outreach, the Board made changes to the newsletter, seal, and logo. She added that there has also been an increased presence of the Board on social media. Ms. Robinson explained that under administration, the President's award was established and awarded to Mr. Eslami and Mr. Eichelkraut for the development of the iOS application and desk procedures were revised and are under current review. She concluded by providing highlights of what is to come in 2019.

Agenda Item 13 Update on the Health Professions Education Foundation

Dr. Hawkins reminded the Board that Health Professions Education Foundation (HPEF) is a non-profit entity that improves access to healthcare in underserved areas of California by providing scholarship and loan repayment programs to aspiring and current health care professionals. He shared that HPEF met on January 9, 2019, in Sacramento. He noted that the application cycle for fiscal year 2018 - 2019 opened December 30, 2018 and will close February 27, 2019. He shared that there is a total of $5 million available for loan repayments but the HPEF hopes to expand that amount for the 2019 - 2020 fiscal year.

Ms. Kirchmeyer offered any interested Board Member to assist in scoring the Steven M. Thompson Loan Repayment Program applications, as HPEF is looking for volunteers.

Dr. GnanaDev noted that the program is still not widely known and that there are plenty of funds available.

Ms. Pines adjourned the meeting at 6:21 p.m.

RECESS

Friday, February 1, 2019

Due to timing for invited guests to provide their presentations, the agenda items below are listed in the order they were presented.

Members Present:
Denise Pines, President
Michelle Anne Bholat, M.D., Secretary
Susan F. Friedman
Dev GnanaDev, M.D.
Randy W. Hawkins, M.D.
Howard R. Krauss, M.D.
Kristina D. Lawson, J.D.
Ronald H. Lewis, M.D., Vice President
Laurie Rose Lubiano, J.D.
David Warmoth

Jamie Wright, J.D.
Felix C. Yip, M.D.

Members Absent:
Brenda Sutton-Wills, J.D.
Staff Present:
April Alameda, Chief of Licensing
Mary Kathryn Cruz Jones, Associate Governmental Program Analyst
Christina Delp, Chief of Enforcement
Kimberly Kirchmeyer, Executive Director
Christine Lally, Deputy Director
Victoria Ornduff, Information Technology Technician
Regina Rao, Associate Governmental Program Analyst
Letitia Robinson, Research Data Specialist II
Elizabeth Rojas, Staff Services Analyst
Jennifer Simoes, Chief of Legislation
Kevin Valone, Staff Services Analyst
Carlos Villatoro, Public Information Manager
Kerrie Webb, Staff Counsel

Members of the Audience:
Eric Andrist, Patient Safety League
Carmen Balber, Consumer Watchdog
Gloria Castro, Senior Assistant Attorney General, Health Quality Enforcement Section, Attorney General's Office
Yvonne Choong, California Medical Association
Cheryl Clark, MedPage Today
Zennie Coughlin, Kaiser Permanente
Virginia Farr
Connor Finney, Consumer Watchdog
Kanwar Gill, M.D.
Bridget Gramme, Center Public Interest Law
Leslie Guevarra
Mario Guzman
Virginia Herold
Marian Hollingsworth, Patient Safety League and Patient Safety Action Network
Diane Holzer, Midwifery Advisory Counsel
Carolyn Johnson, KNBC-TV
Wendy Knecht
Jessica Langley, National Healthcare Association
Susan Lauren, Lipo Coalition and Patient Safety Action Network
Patrick Le, Assistant Deputy Director, Board and Bureau Services, Department of Consumer Affairs

Craig Leader, Investigator, Health Quality Investigation Unit, Department of Consumer Affairs
Jerome Lew, Patient Advocate
James Lin
Paul Marchand, M.D.
Lisa McGiffert, Patient Safety Action Network
Michelle Monseratt-Ramos, Patient Safety Action Network
Steve Muni, Supervising Deputy Attorney General, Health Quality Enforcement Section, Attorney General's Office
Kathleen Nicholls, Deputy Chief, Health Quality Investigation Unit, Department of Consumer Affairs
Ludmila Parada
Lesa Pastor, National Health Career Association
Hanna Rhee, M.D., Black Patients Matter
Mike Sanchez, Videographer, Department of Consumer Affairs
Dennis Scully, Investigator, Health Quality Investigation Unit, Department of Consumer Affairs
Tammy Smick, Patient Safety League
Mark Scarlett, Supervising Investigator, Health Quality Investigation Unit, Department of Consumer Affairs
Anne Sodergren, Interim Executive Officer, Board of Pharmacy

Agenda Item 14 Call to Order/Roll Call/Establishment of a Quorum

Ms. Pines called the meeting of the Medical Board of California (Board) to order on February 1, 2019, at 9:04 a.m. A quorum was present and due notice was provided to all interested parties.

Agenda Item 15 Public Comments on Items not on the Agenda

Ms. Smick remarked that she would attend the Patient's Advocate meeting in the day with recommendations to the Board about disciplinary guidelines, transparency, and timelines. She provided more details about her son, his treatment by Dr. Headrick, and her experience with her complaint with the Board. She pointed out that it took four years to reach a decision and almost two years to interview Dr. Headrick, which in a death case this is unacceptable. She shared that the ultimate decision was a public reprimand, which does not follow the disciplinary guidelines and is a weak form of discipline. Ms. Smick concluded by asking Members of the Board to attend the patient advocate meeting and emphasized the importance of what the advocates have to say.

Mr. Andrist reported that for the December Board meeting it was $4,314 for the room and phone line, which he noted is very expensive and additionally the location and parking were terrible. He commented that the costs of this meeting were out of line and there are plenty of other options that are far more affordable. He provided an update on his website, noting the increased amount of viewers and shared a letter that he received from a Drug Enforcement Administration compliance assistant from an independent pharmacy website. He explained that he has gotten many letters like

this, thanking him for his work and sharing their grievances about the Board. Mr. Andrist concluded by inviting the Board Members to work with the patient advocates versus ignoring them.

Dr. Rhee, Black Patients Matter, called for the resignation of Dr. Nuovo since he represents an outdated and non-diverse part of California's healthcare history. She shared that a colleague from the CMA ethnic, medical organization section was the recipient of biased action in the workplace and in response, she founded the culturally competent mindset. She explained that this individual evaluates, trains, and can certify stakeholders and healthcare leadership. She requested that Black Patients Matter present to the Board on the ongoing racial disparities. Dr. Rhee concluded by calling upon the Board to stop contracting medical experts with no training in racial and religious diversity and to diversify DCA's Division of Investigation.

Mr. Finney, patient's rights advocate with Consumer Watchdog, applauded the Board for creation of the death certificate project and announced that Consumer Watchdog and the Center for Public Interest Law have written a letter in support. He pointed out that as the opioid crisis continues, the Board has taken the necessary steps to hold negligent overprescribing physicians accountable, providing justice for the victims of opioid overdoses, and protecting future patients from being victimized. He added that the interested parties meeting will be a great venue for people to voice their concerns over the Board's effectiveness and urged the Board to make it a regular event and to take the suggestions and complaints seriously. He concluded by urging the Board to support a Bill of Rights for patients, which would allow for more communication and transparency while fulfilling the Board's duty of protecting California patients.

Ms. Knecht explained the details of her complaint that she filed with the Board. She noted that her case has brought to light several issues that she would like to bring forward about Board policies and procedures, including fair and thorough investigations and settlement disclosures. She was pleased to hear that it seems that there will be amendments to the settlement disclosure language and she urged the Board to support legislation that amends settlement disclosure. She recommended that all communications regarding investigations be accessible on a mutual website for patients and parties involved, which is something that the Patent and Trademark Office does. Additionally, she noted that in the meantime investigators really need to update patients periodically and work on stronger communication. Ms. Knecht concluded by asking the Board to address physician conflicts of interest in treatment decesions.

Ms. Hollingsworth, patient safety advocate with the Patient Safety League and the Patient Safety Action Network, brought up the issue of concurrent and superseding disciplines. She provided examples of doctors in San Diego and their outcomes for overprescribing. She inquired how this serves the patient's interest, since it allows the physician to serve their probationary orders at the same time. She pointed out that this seems to be a new pattern that is emerging, and it seems as if the Board is being a bit lenient when it comes to doctors who have clearly violated the standards.

Ms. Lauren provided details of her story, sharing that she was mutilated by a surgeon. She vocalized that it was not something that she had agreed to or asked for, but rather that it was a contraindicated, unwarranted, battery episode that has left her housebound and with a diminished quality of life. She

stated that surgeons should not be given carte blanche to do whatever they would like, but this authority is given by the Board and it is something that the Board allows. She added that the place in which this took place was an ambulatory center that does not undergo any checks and balances. She shared that her legislators have read letters from doctors that have examined her and substantiated the battery done to her. Ms. Lauren commented that the medical examiner from her case slandered her, perjured himself, and provided the rates of his payment. She inquired about the next step that she should take since she has felt blocked by the Board and the Board is covering up a horrific crime of which she is the victim.

Dr. Gill commented that the pool of experts utilized by the Board is not the best and the Board should pay experts at a higher rate. He provided the rates of an expert compared to the defense attorneys and opined that there will be a difference in quality if the rates are increased. For this reason, he asked the Board to consider the cost of prosecuting. He echoed the concerns of a previous public commenter, regarding the expenses associated with Board meetings. He commented on the high cost of the meeting and suggested that the Board put this money toward paying their experts more.

Agenda Item 16 Update on the Board of Pharmacy

Ms. Sodergren from the Board of Pharmacy thanked Ms. Kirchmeyer for her collaboration as issues and challenges arose due to the enactment of AB 1753. She commented that the information sharing and joint statement that both the Board and the Board of Pharmacy released provided reassurances to licensees. She confirmed that the Board of Pharmacy voted to approve AB 149, which would provide a permanent solution to AB 1753 issues. She provided more information about their education and enforcement events, consumer education campaign, and an upcoming education forum for prescribers and dispensers. Ms. Sodergren detailed the Board of Pharmacy supported a policy statement supporting the role of pharmacists providing medication assisted treatment under collaborative practice agreements. She added that the Board of Pharmacy is also looking at steps it can take to improve emergency response and will be sponsoring legislation that will create a very limited exception to the controlled substance prescription forms that are required for patients.

Ms. Choong, CMA, shared the dilemma of how to prescribe controlled substances safely and effectively while simultaneously reducing the risk of prescription medication misuse, addiction, and overdose. She confirmed that CMA is supportive of efforts to address these issues and advocates for a well-balanced approach, considering the unique needs of individual patients. She detailed that CMA is concerned about the impact pharmacy policies are having on the patient's ability to access their medications in a timely manner. She specified that since November, they have received about two dozen calls regarding prescription denials. She pointed out that some physicians have been asked for extensive documentation going beyond corresponding responsibility, which asks the questions of medical record retention and how this material is being handled thereafter. Ms. Choong concluded by expressing CMA’s hope to arrange a convening with pharmacy corporations and stakeholders to reach an agreement about community standards and the responsibility of pharmacists.

Ms. Parada vocalized that she believes it is the view of the Board and the Attorney General's (AG) Office that what happened to her husband is a mistake, but she does not feel the same way. She commented that her husband is paralyzed for life because his doctor repeatedly disregarded his pleas for advice. She thanked Consumer Watchdog for taking interest in his case since it is now known by activists across the nation. She remarked although the Board is a consumer protection agency, the consumer has the lowest of its consideration, which was evident in the case of her husband, who sustained permanent injuries while the doctor responsible did not even get a note on their record. Ms. Parada concluded by noting that there is no transparency or accountability and questioned the protection and justice for the patients.

Ms. Pines recognized Ms. Herold, former executive officer of the Board of Pharmacy, who retired on December 31, 2018, after 39 years of state service, 29 of which were with the Board of Pharmacy. She thanked her for her collaboration and service in working with the Board over the years.

Ms. Herold thanked the Board and remarked that there is much more to be done. She noted the importance of the collaboration between both boards and pointed out that it will be important to maintain this relationship moving forward.

Dr. GnanaDev shared that Ms. Herold was especially helpful to the Board and in bringing together both boards.

Agenda Item 17 Discussion and Possible Action on the Petition Pursuant to Government Code Section 11340.6 to Amend 16 CCR Section 1366.31 Regarding Approved Medical Assistant Certifying Organizations

Ms. Webb explained that the Board received a request to review the requirements for medical assistant certifying agencies. She clarified that medical assistants are not required to be certified to perform their technical supportive services, however, if they are going to train other medical assistants, they have to be certified by an organization approved by the Board. She shared that the National Healthcareer Association (NHA) asked the Board to consider striking the requirement that medical assistant certifying agencies be non-profit. She pointed out that the original purpose of the regulation was to avoid approving agencies with a profit motive and to ensure quality training, however NHA asserts that for-profit entities are creating non-profit arms to bypass that barrier. Additionally, she remarked that being non-profit does not ensure that an organization has good quality and that more needs to be considered.

Ms. Webb elaborated that NHA has suggested that certifying agencies be accredited by the National Commission for Certifying Agencies (NCCA) and undergo psychometric evaluation. She detailed it may not be necessary for certifying organizations to undergo a separate psychometric evaluation since it may already be a part of the NCCA approval process. She confirmed that she has reached out to NCCA and is awaiting their response to obtain more information. She asked the Board to approve the request in concept and to permit staff to bring some proposed regulation language back before the Board for consideration. Ms. Webb suggested that if this regulation is amended for

medical assistant certifying organizations, it should also be done for midwife assistant certifying organizations.

Dr. GnanaDev made a motion to support the request in concept and to permit staff to bring proposed regulation language before the Board for consideration; s/Dr. Lewis.

Dr. GnanaDev commented that many organizations are moving to do the same. He provided examples of Centers for Medicare and Medicaid Services as well as Liaison Committee on Medical Education (LCME). He remarked that it is a trend and potentially a legal liability. He highlighted the important of the accrediting agency and suggested that if they are a good agency he would not have any problems.

Mr. Warmoth agreed with the concept of the certifying agency to consider the training programs but inquired why it would also require that the Board do away with non-profits.

Ms. Webb answered that for-profit entities are creating non-profit arms to avoid the barrier. She added that this is to address concerns about the quality of the training versus running a certification mill.

Mr. Warmoth remarked that although he does understand the point being made, he does not believe that the Board should remove the non-profit requirement. He stated that the addition of the accreditation process can happen without striking non-profits.

Ms. Webb responded that the appropriate route is to ensure the quality rather than maintaining a barrier as to who can perform certification.

Dr. GnanaDev commented that Mr. Warmoth's point is a good one and he too had similar thoughts. He explained that LCME took out one of the requirements that their parent company of a medical school should be a not-for-profit entity. He added the concern that the Department of Education is approving for-profit entities. He expressed the need to look at quality, his aversion to for-profit entities, and that this is an issue that has come up in multiple places.

Dr. Bholat asked for more clarification about the certification and what the Board is certifying. She asked for confirmation as to whether it was the certification for the medical assistant to teach another group of medical assistants or if the certification is for the training school for the medical assistant.

Ms. Webb confirmed that it is not certifying schools, it is certifying the individual. The purpose is to be able to have a medical assistant in the office who can train other medical assistants.

Dr. Bholat asked if the motion is intended to help improve the variation in quality.

Ms. Webb responded that part of why there is so much variation for medical assistants is because there is no requirement for formal training. For example, they can be trained on the job and they do not have to go to school. She confirmed that this motion does not address the schooling required,

rather it addresses the individual coming out of the school and the requirements that they must meet to be certified. She remarked that the motion relates to the certifying organization.

Dr. Bholat recommended that moving forward the Board should discuss the role of a medical assistant, consequences of working outside of the scope, and the costs of certification. She commented that generally medical assistants are people from the communities of color and the certification process is quite costly.

Dr. Krauss requested that in reporting back, Board staff touch on the differences between non-profit and for-profit in terms of the influence on consumer costs. He commented that there is $3.3 trillion spent on healthcare in the United States, however he believes that only a fraction of it goes to healthcare and that the majority goes to profit, administration, and regulation. For this reason, he asked that Board staff look into increased costs down stream as accrediting agencies become for-profit. He also asked for more information regarding the benefit of non-profit status, since oftentimes non-profits have obligations to the government and fall into certain regulatory rules, which might not be the case in for-profit entities.

Dr. Yip echoed the request about more information regarding medical assistant training. He added that there are implications as to where an entity is for-profit or non-profit. He remarked that more details need to be looked into due to the large range of specialties that exist. He explained that more information needs to be given as to how the medical assistants are trained and certified.

Dr. Rhee, Black Patients Matter, requested that medical assistants be required to be accredited and certified to maintain healthcare standards. She noted that once certified, they should be required to undergo training in racial and religious diversity. She opined that in her own experience, there is a difference between certified and uncertified medical assistants and their level of quality. She agreed with Dr. Bholat and suggested that there be a cost containment solution since many medical assistants struggle with costs and come from young, working-class, immigrant communities.

Motion carried unanimously (12-0).

Agenda Item 18 Presentation on Outpatient Surgery Settings

Ms. Kirchmeyer and Ms. Alameda provided a presentation on outpatient surgery settings and the Board's role in their oversight. Ms. Kirchmeyer began by explaining the court decision that changed the role of the Board in the oversight of these facilities. She explained that the law states that if a surgical procedure uses anesthesia to be administered in doses that have the probability of placing a patient at risk to lose their life preserving reflexes, the surgery must be performed in an accredited, licensed, or certified setting. She elaborated on the process of accreditation and commented that the Board has approved five different accreditation agencies. She specified that the Board does not issue the facility accreditation; rather the Board approves the accreditation agency that accredits the outpatient surgery settings.

Ms. Alameda discussed the evolution of the outpatient surgery settings, noting that the program was enacted in 1995, at which time the Board approved four accrediting agencies. She shared that today, the Board has 900 accredited settings and there are a total of 1,300 in the Board's database.

Ms. Kirchmeyer noted the case, *Capen v Shewry*, mandated that even if 1% of the outpatient surgery setting was owned by a physician, then the facility needed to be overseen by the Board and not CDPH, who provides licensure to these facilities. She explained that in meetings between CDPH and the Board, it was determined that CDPH was not going to license any entities that had any physician ownership, but rather they would be under the jurisdiction of the Board.

Ms. Alameda shared information about the change in legislation that produced more oversight. She discussed how this changed the roles and responsibilities for the Board, the outpatient surgery setting, and the accreditation agencies. She discussed the implementation and the achievements of the Outpatient Surgery Setting Task Force, which helped better the outpatient surgery setting program. She walked through the database and shared with the Board that there may be updates in the future to allow Board staff to process the information shared more promptly. Ms. Alameda concluded with a side-by-side chart of the roles and responsibilities of the accrediting agencies and the Board and walked through the process for an outpatient surgery setting if it has received a deficiency after an inspection.

Ms. Kirchmeyer provided information regarding adverse event reporting, sharing the specific details about when to report. She noted the seven types of mandatory reporting: an issue occurring during or after a surgical or other invasive procedure, an issue occurring with a product or device, an issue related to patient protection, an issue occurring with care management, an environment related event, a criminal matter, and an issue that causes the death or serious disability of a patient, personnel, or visitor. She then provided information about the reporting process, noting the role of the Board, the setting, and the accrediting agency. Ms. Kirchmeyer concluded by providing statistics about adverse event reporting from fiscal year 2013 - 2014 to the present.

Dr. Hawkins inquired about the length of time it takes to settle outpatient surgery setting cases.

Ms. Kirchmeyer responded that if it is a case against the physician, it is about 140 days for review, about 500 days if it warrants investigation, and 400 days for an accusation. She pointed out that the timeframe for accrediting agencies to investigate is 30 days.

Ms. Webb clarified that this timeframe is shorter if it is an urgent case.

Ms. Kirchmeyer agreed, that it is five days in the case of an urgent matter.

Dr. Yip disclosed that he is a shareholder at a surgery center where he performs ten cases a year. He inquired how many accusations result from the activity review.

Ms. Kirchmeyer responded that she would follow up with him.

Dr. Yip asked about the amount of Board staff that assists with the outpatient surgery settings program.

Ms. Kirchmeyer stated there is currently one person from licensing and one from enforcement.

Dr. Yip recommended that the accrediting agency require that on discharge paperwork for the surgery setting that they put a note about the Board providing oversight of the centers.

Ms. Kirchmeyer thanked Dr. Yip for the idea and noted that this may be a future change. She confirmed that if a physician works in the setting, there must be a sign posted or acknowledge this in paperwork. She added that the patient will be notified of the physician in one of the two ways.

Dr. Yip mentioned that he does not know if it would be posted in the surgery center.

Ms. Kirchmeyer stated that it should be, since it is a requirement of the physician and not the facility.

Ms. Webb confirmed that the sign must be posted in the practice location.

Ms. Kirchmeyer shared that the posting in the practice location is something that the Board needs to remind physicians, as well as the public about, and for this reason, there will be an article in the newsletter as well as tweets on social media and blasts to licensees in order to help disseminate the information. She also mentioned that there is a requirement that the setting must post who accredits them and that complaints go to that accrediting agency, who will then notify the Board.

Dr. Krauss stated his conflicts of interest, noting ownership interest in an ambulatory surgery center and that he was a past member of the board of the California Ambulatory Surgery Association. He questioned if this is an unfunded mandate, and if it is, he recommended that the Board speak to legislators about having fees for this program. He expressed that although he understands the intent of the law, he has the impression that there are many procedures done in offices without oversight. For this reason, Dr. Krauss recommended that the Board work with legislators and regulators to better define what may be safely done and may not be safely done in the office setting. He questioned if the death certificate project could be applied to the outpatient surgery centers, using death certificates to see if further investigation is needed. Dr. Krauss concluded, noting his frustration in the different reporting requirements between hospital outpatient departments and ambulatory surgery centers and he noted the benefit to the public if the requirements were the same.

Ms. Kirchmeyer responded that when the accreditation agency renews with the Board, there is a fee that they must pay, and therefore there are some fees that are given to the Board from this program. She agreed with Dr. Krauss that there is a problem with oversight in the various settings. She noted that this is something that can be handled through legislation and something that the Board can discuss moving forward in order to clear up the gray areas. She commented that with regard to the death certificates, she is not sure if any information can be obtained, but she would have a conversation with CDPH in order to obtain more information. Ms. Kirchmeyer agreed that agencies

with differing requirements pose difficulties and added that this too is potentially something that can be investigated.

Ms. Lubiano asked for more insight as to why there was an increase in adverse event reporting in the last four years.

Ms. Kirchmeyer responded that the first year reported was only a six month timeframe for the data due to the timing of the fiscal year and when the law required the reporting. She added that the real increase was with the change in law to include patient transfers. She shared that this number will likely increase in the year to come.

Dr. Bholat asked for more clarification as to what transfers meant.

Ms. Kirchmeyer explained that due to conversations with interested parties, the law now includes transfer of a patient to a hospital or emergency center for medical treatment for a period exceeding 24 hours following a procedure in an outpatient surgery center.

Dr. Bholat inquired how many of the outpatient surgery centers have deemed status.

Ms. Kirchmeyer responded that this is information that can be provided to her later.

Dr. Gill questioned if the adverse event reporting and enforcement is any different for hospital owned facilities versus physician owned facilities. He then asked after an investigation of a setting is complete, and a closure report is submitted, if the Board can reopen the investigation.

Ms. Lauren, provided details about the ambulatory center and the physician that surgically assaulted, disabled, and disfigured her. She shared her experience after her surgery and noted the issues she found. She provided insight into what her life was before the surgery and highlighted the differences between what her life looks like after the surgery. She commented that the physician did not file an adverse event report, but he did fabricate her records. Ms. Lauren confirmed that she was pressured and coerced into the procedure and she noted that this is widespread and many other women have similar stories. She shared that the adverse reporting that was presented does not even happen since so few people report it.

Agenda Item 19 Discussion and Possible Action on Recommendation from the Special Faculty Permit Review Committee

Dr. Bholat reported that on December 7, 2018, the Special Faculty Permit Review Committee (Committee) held a teleconference meeting to review and discuss the appointment of Dr. Fabrizio Luca as Chief of Colorectal Surgery at Loma Linda University School of Medicine (LLUSM). She explained that Dr. Luca currently holds a Special Faculty Permit and therefore he must be approved by both the Committee and the Board to be appointed to the Chief position. She detailed that Dr. Luca's area of expertise is in robotic rectal cancer surgery. She shared Dr. Luca has assisted in advancement and development of robotic programs in the specialty of colorectal esophageal gastric

and pediatric surgery, and he is working on implementing an enhanced recovery after surgery protocol. Dr. Bholat concluded by noting that if approved by the Board, Dr. Luca will serve as the Chief of Colorectal Surgery at LLUSM and remarked that the Committee has reviewed his qualifications and recommends that the Board approve Dr. Luca for this appointment.

Dr. Bholat made a motion to approve Dr. Luca to appointment as the Chief of Colorectal Surgery at LLUSM; s/Dr. Krauss.

Dr. Rhee, Black Patients Matter, expressed her concerns that Dr. Luca may not have previously treated African Americans and may not have interest in learning.

Motion carried unanimously (11-0, Wright absent).

Agenda Item 20 Update, Discussion, and Possible Action of Recommendations from the Midwifery Advisory Council Meeting

Ms. Holzer requested approval on items for the next Midwifery Advisory Council (MAC) meeting. She listed the items of approval, including discussion on establishing 2019 goals for the MAC, update on MAC related legislation, selection of new members and a Vice Chair for the MAC, discussion and possible adoption of an administrative procedures manual, and selection of 2019 MAC meeting dates. She added that other items pending approval include report from the MAC chair, update on the midwifery program, and discussion of actions to improve services for midwifery clients. She shared that at the last meeting the MAC did not have a quorum, and therefore no actions were taken.

Dr. GnanaDev made a motion to approve the proposed topics for the next Midwifery Advisory Council meeting; s/Dr. Lewis.

Dr. Hawkins inquired why the MAC did not have quorum at the last meeting and asked if they anticipate this being a problem moving forward.

Ms. Holzer confirmed that it will not be a problem moving forward.

Ms. Kirchmeyer explained that there were airline complications that impeded a member from being present at the meeting.

Motion carried unanimously (10-0, Lawson and Wright absent).

Agenda Item 21 Discussion and Possible Action to Amend Title 16, California Code of Regulations, Section 1321 Regarding Postgraduate Training

Ms. Webb announced to the Board that there was confirmation that legislation will be introduced to clarify that the Board will be approving the postgraduate training for combined programs in dental and medical, for the oral and maxillofacial surgery residency programs. She noted that this was brought forward to add that to a rulemaking that the Board has already approved. She concluded that this item is not necessary at this time.

Dr. GnanaDev acknowledged that the issue is that Loma Linda oral surgery residents rotate through his department. They are both a doctor and a dentist with dual degrees. For this reason, he wants to ensure that they are not affected by requirements they cannot meet.

Agenda Item 22 Update from the Enforcement Committee

Dr. Yip stated that at the Enforcement meeting the day prior, Ms. Delp provided an update on enforcement statistics and timelines. Additionally, Ms. Delp discussed the implementation of SB 1448, and the transition from the vertical enforcement program. He noted that Mr. Chriss and Ms. Nicholls presented on HQIU's current workload and vacancy rates. He added that Ms. Moore, Ms. Westfall, and Ms. Alvarez provided a presentation on the disciplinary process. Dr. Yip encouraged his fellow Members to read the January 18, 2018 meeting minutes since they are similar to an instruction booklet on the Board's enforcement process.

Agenda Item 23 Update from the Attorney General's Office

Ms. Castro provided information about the history of the Health Quality Enforcement Section (HQE) staff, and their duties. She provided insight into how HQE is transitioning with the Board after the changes made to vertical enforcement. She explained that HQE is working to absorb the 1.9 million-dollar budget cut. Additionally, HQE is preparing for probation notification pursuant to SB 1448 as well as expert report exchanges under B&P Code section 2334. Ms. Castro announced that the AG's Office published its second annual report. She noted that this report highlights statistics regarding withdrawls, accusations, reviews, rejects, and accusations filed. She concluded by sharing that Deputy Attorney General Richard Marino retired and Deputy Attorney General Cindy Lopez will also be retiring and leaving the AG's Office.

Dr. Yip thanked Ms. Castro for her hard work. He then asked if there was a way in which the status of a case could be tracked similar to how a person can track an Amazon package.

Ms. Castro responded that this would not be a challenge to complete, but that it could take away from the focus of processing the case. She added that if there is interest in this being done, it is something that could potentially be done.

Dr. GnanaDev acknowledged the budget cuts to HQE. He questioned if the AG's Office is involved with the DEA and the federal government to control street opioids. He added that with prescription opioids there is knowledge of how much is taken, but with the street opioids this information is unknown.

Ms. Castro commented that currently there are 50 vertical enforcement investigations that are jointly assigned between HQE and HQIU. She noted that this process will continue and HQE will be responsive to any requests in the future. With regard to Dr. GnanaDev's question, Ms. Castro shared that when Ms. Harris was the Attorney General, the Bureau of Narcotics Enforcement was removed from the AG's Office. She added that Mr. Becerra is committed to finding resolutions to the opioid epidemic. Ms. Castro confirmed that she will share the concerns with the AG.

Dr. Lewis commented that it is great to take action within California, but that there needs to be a partnership with the federal government to put pressure on China, since much of the illegal street drugs are coming in and killing citizens within the United States.

Ms. Kirchmeyer asked that Ms. Castro thank Ms. Lopez for all her work and service to the Board.

Dr. Rhee, Black Patients Matter, expressed her deep concern over the lack of racial diversity at the AG's Office. She commented that there are studies emerging that demonstrate that African-American physicians are being targeted, which in turn discriminates against black patients. She added that steps need to be taken to close the racial disparity and provided examples of what could be done.

Dr. Gill shared that California is one of the very few states that has not sued Purdue pharmaceutical, the company that manufactured oxytocin, however there are over 30 counties within California that have filed lawsuits. He asked that this be taken back as a message. He added that the vertical enforcement program was started as a vertical prosecution program. He commented that intent of the program was a political agenda that was forced upon physicians and lasted almost twelve or fourteen years. Dr. Gill vocalized his support for the end of this program, since the Board could not ensure consumer protection.

Ms. Gramme, Center Public Interest Law, explained that she was glad to hear that the Board and Ms. Castro are still working together, since it is an important part of consumer protection. She encouraged the two parties to continue working together.

Ms. Andrist reminded that Board that at the last meeting he asked for an update from Ms. Castro on an item that Judge Feinstein had mentioned in the January 2017 meeting. He then discussed the details of several cases that the Board processed.

Agenda Item 24 Update from the Department of Consumer Affairs, which may include updates on the Department's Administrative Services, Human Resources, Enforcement, Information Technology, Communications and Outreach, as well as Legislative, Regulatory, and Policy Matters

Mr. Le welcomed the two new Board Members and provided highlights from 2018, including nine licensing and enforcement workgroups, four Director's quarterly meetings, and two Director's teleconference leadership calls. He notified the Board that the DCA Annual Report is now online and provides information on all 38 boards, bureaus, and commissions. He assured Board Members that there is no action required from current gubernatorial appointees due to the change in Governor. Mr. Le discussed the Governor's 2019 - 2020 budget, which outlines fiscal priorities including paying down debts and pension obligations, building reserves, and making investments in healthcare, childcare, preschool, and higher education.

Mr. Le continued to discuss AB 2138, the bill that relates to a board's ability to deny a license based on past criminal convictions and noted that DCA released a draft timeline with dates to help stay on

track for the July 2020 implementation date. He pointed out that action will need to be taken by all boards in May 2019 to be ready for the July 2020 deadline. He added that DCA has created potential model regulations and will try to assist in collecting data for the reporting requirements.

Mr. Le provided an update on the Substance Abuse Coordination Committee (SACC), which is made up of the healing arts executive officers. The SACC was established to examine the way boards deal with substance-abusing licensees and shared that there have been two technical changes in the Uniform Standards the SACC developed. The first is adding language that allows a board to approve alternative drug testing locations and alternative testing frequencies for a licensee who is going on vacation or taking a leave of absence. He explained that the second is a policy addition that allows the healing arts boards to lower the drug testing frequency to not less than twenty-four times per year if the licensee has a required supervisor. He noted that the SACC determined that several other standards need to be reviewed, and therefore there will be additional meetings in 2019.

Mr. Le updated the Board that the executive officers' salary study is expected to be complete in March 2019. He remarked that an initial review has been conducted with executive officers to identify themes, challenges, and expected outcomes.

Mr. Le provided administrative reminders, noting that that Board Member Orientation Training is a one-day training that is mandatory for all new appointments, or those that have been reappointed. The second reminder was to file the annual statement of economic interest also known as form 700, which is due on April 2, 2019. He concluded by reminding the Board of the mandatory sexual harassment training due this year.

Ms. Pines inquired about the union representative who spoke about the reclassification of inspectors, since she thought that it was pending with DCA.

Mr. Le said that he could not speak about it, however he would bring it back to Human Resources at DCA.

Dr. GnanaDev asked if the six-month timeline for the executive director's salary is an accurate timeline.

Mr. Le confirmed that the timeline is accurate. He articulated this study has taken so much time because salary increases involve many layers of review such as agency, and the Governor's Office, and in addition to this, the study is also examining the complexities of the job duties, a look at what is being done in other states, and gender parity.

Dr. GnanaDev reminded Mr. Le that the Board is the largest board in the country. He added that one out of six doctors are licensed in California. He expressed his frustration since the money for the study is not coming from general fund, rather it is coming from the Board, and this study has taken a long time to complete with no resolution. Dr. GnanaDev also noted that many patient advocates complain that they are not interviewed by investigators, and inquired why HQIU could not do this.

Mr. Le remarked that he would pass on the concern to HQIU.

Dr. Bholat requested more information about the decision to change the uniform standards to decrease urine toxicology screening for patients that have addictions.

Mr. Le answered that the SACC was a result of SB 1441 and is made up of all the executive officers of the healing arts boards. He explained that the testing standard has remained the same; just an exemption has been created. This exemption was to consider the fact that there are different types of testing, different cost structures associated with different types of testing, and experts have found that random sampling is just as important as frequency. The number can be lowered, but they must be monitored by their workplace.

Dr. Rhee, Black Patients Matter, explained some of her concerns with DCA, including their misuse of power by targeting underrepresented minority physicians, which care for underrepresented minority patients, therefore marginalizing and discriminating against patients. She commented on DCA being non-diversified, which makes it evident why minorities are unfairly targeted in the investigative process. She provided examples of the non-diversified work culture at the Division of Investigation. She continued to provide the story of a patient who was mocked, ridiculed, and cursed at and added that Black Patients Matter submitted multiple complaints to DCA with no response. Dr. Rhee concluded by vocalizing her concerns that complaints involving black patients are marginalized by DCA and are not prioritized.

Mr. Andrist suggested that the Board obtain training in sexual harassment complaints and provided an example of a past case that came before the Board. He compared that profile of the doctor in his website, which has all of his convictions, as opposed to the Board's website, which has none of his convictions. He shared that he knows that sexual misconduct cases are supposed to be a priority, however he believes that they are not being taken seriously.

Dr. Gill spoke about a complaint that involved Stanford and the University of California, San Francisco trained physicians that indulged in a practice of medicine that was below the standard of care. He shared that he had spoken with the investigator and learned that there was evidence beyond reasonable doubt, sufficient for a criminal conviction. He explained that the investigation was turned over to another investigator and after that the case was closed. Dr. Gill confirmed that he was the complainant in the case and he was never interviewed, which means that HQIU is not investigating the complainants.

Agenda Item 25 Future Agenda Items

Dr. Hawkins requested a presentation on the utilization of pre-exposure prophylaxis (PrEp) to prevent new HIV infection in high-risk groups.

Dr. Bholat asked for a presentation on the X Waiver and the use of buprenorphine to see if at the state level there is another approach to decrease the access barrier.

Mr. Warmoth stated he valued public comments that are received and noted that they are very helpful. He asked that staff develop a best practices document on how to most effectively testify to the Board.

Mr. Andrist discussed his concern regarding public censorship and requested that the Public Meeting Act be placed on the agenda.

Ms. Hollingsworth shared her concern over censorship and freedom of speech. She shared that the Board is monitored so that it can make changes so that certain physicians will not continue to harm people.

Dr. Gill asked for a presentation on the role of CDPH. He explained that the reason he would like this discussion is to clarify that licensed facilities can be making mistakes and it is not always the physician working in the facility that is committing all the errors and mistakes.

Ms. Monseratt-Ramos vocalized her frustration that DCA has made no effort to incorporate a telephone line to allow the public and stakeholders to participate in SACC meetings in real time. She added that she was informed by Mr. Le that the change in the number of random drug testing would only affect certain licensees, however today at the meeting before the Board he announced that this change would affect all licensees. She noted that this makes it feel relative to physicians, when it should not be.

Agenda Item 26 Adjournment

Ms. Pines adjourned the meeting at 12:05 p.m.