

## MEDICAL BOARD OF CALIFORNIA OUARTERLY BOARD MEETING



Crowne Plaza San Jose –Silicon Valley 777 Bellew Drive Milpitas, CA 95035 January 18 – 19, 2018

#### **MEETING MINUTES**

Thursday, January 18, 2018

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

#### **Members Present:**

Dev GnanaDev, M.D., President Michelle Anne Bholat, M.D. Randy W. Hawkins, M.D. Howard R. Krauss, M.D. Ronald H. Lewis, M.D., Secretary Denise Pines, Vice President David Warmoth Jamie Wright, J.D. Felix C. Yip, M.D.

### **Members Absent:**

Kristina D. Lawson, J.D. Sharon Levine, M.D. 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
Regina Rao, Associate Governmental Program Analyst
Letitia Robinson, Research Program Specialist II
Elizabeth Rojas, Staff Services Analyst
Jennifer Saucedo, Staff Services Analyst
Jennifer Simoes, Chief of Legislation
Carlos Villatoro, Public Information Manager
Kerrie Webb, Staff Counsel

#### Members of the Audience:

Megan Allred, California Medical Association

Lynne Andres, California Academy of Physician Assistants

Eric Andrist, via phone

Nika Avila, via phone

BJ Bartleson, California Hospital Association

Gloria Castro, Senior Assistant Attorney General, Health Quality Enforcement Section (HQES), Attorney General's Office (AGO)

Zennie Coughlin, Kaiser Permanente

Matt Davis, Supervising Deputy Attorney General, HQES, AGO

Rosanna Davis, L.M., California Association of Licensed Midwives

Lynn Forsyth, Executive Officer, Physician Assistant Board

Louis Galino, Videographer, Department of Consumer Affairs (DCA)

Fred Gardner, Society of Cannabis Clinicians, via phone

Marianne Gausche-Hill, Los Angeles County EMS Agency, via phone

Stephen G. Henry, M.D., University of California, Davis

Andrew Hegelein, Northern Area Commander, Health Quality Investigation Unit (HQIU), DCA

Marian Hollingsworth, via phone

Ralph Hughes, Investigator, HQIU, DCA

Todd Iriyama, Special Investigator, HQIU, DCA

Clayton Kazan, Los Angeles County Fire Department

Saskia Kim, California Nurses Association, via phone

Brandon Klug, Medic Ambulance Service

Alex Kobayashi, Staff, Office Senator Jerry Hill, via phone

Susan Lambe, Hospital Council of Northern California, via phone

Susan Lauren, via phone

James Lin, M.D., via phone

Kevin Mackey, President of the Emergency Medical Directors Association of California, via phone

Tim Madden, California Chapter of American College of Emergency Physicians

Ken Miller, M.D., PhD, Santa Clara County EMS

Michelle Monseratt-Ramos, Consumers Union Safe Patient Project, via phone

Kathleen Nicholls, Deputy Chief, HQIU, DCA

Rose Neilan, via phone

Stephen Robinson, M.D., Society of Cannabis Clinicians, via phone

Donna Seitz, Los Angeles County, via phone

Carrie Sparrevohn, L.M., Midwifery Advisory Council

Lawrence Stock, past President of California Alcohol and Substance Abuse Programs, via phone

Brentston Taylor, Special Investigator, HQIU, DCA

Kayla Watson, Center for Public Interest Law

Clement Yeh, San Francisco Fire Department, via phone

Jane Zack Simon, Supervising Deputy Attorney General, HQES, AGO

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

Dr. GnanaDev called the meeting of the Medical Board of California (Board) to order on January 18, 2018, at 3:40 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

Ms. Avila, detailed her experience as a licensed massage therapist. She noted, one of her clients, Susan Lauren, does not feel like other bodies she has felt in the past. Ms. Avila provided more detail as to what she believed is the cause of this. She commented that Ms. Lauren's tissue has no elasticity and is overly sensitive. She spoke to the type of person that Ms. Lauren is and concluded that she would have never agreed to the kind of surgery that was performed on her.

Ms. Hollingsworth noted that she was representing herself on the call, and stated that in light of the #Me Too Movement, she requested that the Board take up the issue of requiring doctors on probation for sexual misconduct to tell their patients. She added, that last year the Board voted to endorse a bill that would have required patients to be notified. Unfortunately that measure failed in the legislature due to interference from the California Medical Association (CMA). Ms. Hollingsworth mentioned that CMA is a doctor lobby group that only represents one third of doctors in the state. She elaborated that a bill or permission from the CMA is not necessary to require doctors found responsible for sexual misconduct to tell their patients. This decision can be made by the Board.

Ms. Hollingsworth stated that any discipline can include a condition to notify patients. Ms. Hollingsworth remarked that the Board has done this before with doctors in gross negligence cases, so there is no reason why the Board cannot make this requirement for sexual assault cases. Ms. Hollingsworth added that it is the Board's mission to protect patients, but the Board is not doing the job properly, if doctors are able to hide their discipline. Women and men cannot protect themselves and make decisions in their own care if they do not know about their doctors. She mentioned that although the information is on the website, the reality is that no one will look up their doctor before every single appointment like the Board expects consumers to do. She added that she could not imagine any female Member of the Board being okay with not knowing if her doctor is on probation for sexual misconduct. Similarly, she could not imagine that any male on the Board not wanting to protect their wife, daughter, or mother. She added that she hoped the Board would decide on their own to have the doctors notify their patients, or at least have an agenda item at the next Board meeting.

Mr. Andrist mentioned issues that he encountered in previous meetings in regard to his speaking time. He noted that the Board cannot enforce the requirement that prohibits the public from speaking about open complaints. According to the Brown Act, the public can talk about anything they want in at a public meeting as long as it is on topic. He also inquired if Board Members received their informational packet he provided at the October Board meeting.

Mr. Andrist provided his website <a href="www.4patientsafety.org">www.4patientsafety.org</a> and noted several problems with the Board's website and the documents that are not posted. He added that the Board should be more careful and take time to actually read all the documents. He stated he had found several errors in documents posted online. In addition, he added that Members have been told that the Board's Counsel has been breaking the Public Records Act and yet there are no changes.

Mr. Andrist shared his recent experiences with public document requests he made to the Board. He noted that documents he requested should have already been made public, and were not. He

added, documents required by law are not only missing from BreEZe, but the Board is incapable of finding them. Mr. Andrist inquired about the accountability for this transgression.

Mr. Gardner, Society of Cannabis Clinicians (SCC), requested that the Board include a discussion of both appendices to the Guidelines of for the Recommendation Purposes at the next meeting. Mr. Gardner noted issues in Appendix 1, the Decision Tree, which contradicts the Guidelines. He added that Appendix 2, the cannabis agreement, was modeled on a document in which patients being prescribed narcotic opioids acknowledged the risks. He stated cannabinoid use and cannabinoid users do not face equivalent risks. Mr. Gardner stated that the SCC will provide more information for the Board's consideration and requested it be an agenda item for the April Board meeting.

Ms. Lauren asked what comments are appropriate regarding open and closed complaint cases.

Ms. Webb explained that the public is able to speak about closed complaints.

Ms. Lauren noted that her complaint is still open, and therefore she will proceed to talk about other things regarding the issues. She discussed a doctor that reviews cases for the Board. She elaborated on her negative personal experience with him during a legal deposition. She commented that the litigation process antagonizes victim blame, slander, and shame.

Ms. Lauren continued that although she cannot speak about her case, she too would like to speak about the #Me Too Movement. She stated that the time is up for surgical mutilations of people that go in for either breast reductions or other plastic or reconstructive surgery. Ms. Lauren expressed that board certified surgeons are given carte blanche. An article in Anesthesiology Now from May 2012 notes that for the last several decades nothing has changed. She noted that many people are being harmed by board certified plastic surgeons. She requested that California Code of Regulations, Title 16, Section 1356.6 be discussed as an agenda item at a future Board meeting.

Ms. Lauren added the surgeons are doing procedures that are against need and consent while men and women are unconscious under anesthesia. These actions that surgeons are taking are not medically justified, they are going on egregious sculpting trips, and then they are covering up what they are doing.

Ms. Lauren noted that she has started a group called Lipo Coalition. She added that a lot of people, in California especially, but really all over this country and in different countries are being harmed by board certified plastic surgeons. There are also cover ups, and she is a witness to it directly. Ms. Lauren commented that is it is reprehensible.

## Agenda Item 3 Approval of Minutes from the October 26-27, 2017 Quarterly Board Meeting

Dr. Lewis made a motion to approve the October 26-27, 2017 meeting minutes; s/Dr. Krauss.

Dr. Robinson, SCC, reiterated that that SCC would like to submit commentary on the Guidelines for the Recommendation of Cannabis for Medical Purposes. The SCC has taken issue with

contradictory information in Appendix 1, the Decision Tree, and the Guidelines. He requested that this be placed as an agenda item for the next Board meeting for further discussion.

Mr. Andrist added that the Board cannot continue to tell people that they cannot talk about open complaints. A law needs to be quoted if it is going to be said, because according to the Brown Act the public can talk about anything they want. Mr. Andrist specifically inquired why the public is not allowed to talk about open complaints.

Ms. Webb replied that she has already provided Mr. Andrist the authority in writing.

Mr. Andrist continued with a comment on the minutes. He stated that whoever puts together the minutes usually does an excellent job and with great deal of specificity about what everyone says. He added that he noticed this time something was missing. Mr. Andrist stated he was speaking of Dr. Harri Reddy sexually assaulting four female patients and the minutes reflect what was said. However he noted that when he spoke about how Dr. Dev GnanaDev, the Board President, sat on the panel that restored his license, this information was missing from the minutes. Mr. Andrist inquired why his comments were excluded. Mr. Andrist pointed out that in leaving it out, it has been required to be spoken about again publically and it will have to be reflected in this meeting as well.

Mr. Andrist added that he referred to a website that is better than BreEZe and he lists the web address, but the web address is not listed in the minutes. He commented that the website helps keeps patients safe when the Board website fails. He continued that this information helps keep the public safe and for this reason it should be included in the minutes. The web address is www.bitly.com/doccaught.

Mr. Andrist detailed that on page seven of the meeting minutes Prem Reddy's first name is misspelled. Mr. Andrist elaborated that on page 40 of the minutes, he asked for the Public Records Act to be put on the agenda and it was not. He stated that he has now asked at five meetings for it to be put on the agenda and the request is continually ignored. He noted that he will ask for it again and will continue to ask for it until it is finally added.

Motion carried (7-0-2 – Wright and Yip abstain).

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

Dr. GnanaDev mentioned that he and Ms. Pines had calls with Executive Staff to discuss the meeting agenda and other Board projects. In addition, calls were also made between Dr. GnanaDev and the Executive Staff to review issues that had come to the attention of the Board.

Dr. GnanaDev noted Ms. Sutton-Wills will join Panel A. This change would be effective the January 22, 2018.

Dr. GnanaDev added that the strategic plan was finalized. He noted that staff will work on the finishing touches and provide a final document at the April Board meeting.

Dr. GnanaDev noted that in reviewing this year's Annual Report, the Board issued more revocations and surrenders combined than any year in the last 14 years. In addition, the Board placed more individuals on probation and issued more licenses. Overall, it was a very successful year. Dr. GnanaDev encouraged all Members to ensure they review the Board's Annual report.

Dr. GnanaDev detailed that over the next quarter, he will be meeting with the Governor's Office to discuss issues left from the sunset review, including the vertical enforcement program and the expert reviewer program and will provide updates to the Board as these meetings occur.

Dr. GnanaDev congratulated new Licensing Chief, Ms. Alameda.

### **Agenda Item 5 Board Member Communications with Interested Parties**

Dr. GnanaDev mentioned that as a part of his job he meets with several members from advocacy groups like CMA (California Medical Association), AMA (American Medical Association), the Governor's Office, and Department of Consumer Affairs (DCA).

### **Agenda Item 6 Executive Managements Reports**

Ms. Kirchmeyer congratulated Ms. Alameda who was appointed as Chief of Licensing in December. Under Ms. Alameda's leadership and assistance, the number of days to review an application in the Board's Licensing Unit is 28 days and has been for almost a year.

Ms. Kirchmeyer introduced the new Public Information Officer, Mr. Carlos Villatoro. She added that Mr. Villatoro has begun revising the Board's Newsletter, providing more information via the Board's Twitter account, and is preparing for podcasts and videos on the Board. At a future meeting he will present ideas to the Board's Public Outreach, Education, and Wellness Committee.

Ms. Kirchmeyer mentioned that the Board is still unable to obtain budget details since DCA is switching to a new accounting database, and, at this time, the Board is still uncertain as to when the reports will be available. Therefore, there is no information on the Board's expenditures for fiscal year 17/18.

Ms. Kirchmeyer stated that Dr. GnanaDev and Ms. Pines had discussed the budget increase of the Health Quality Investigation Unit (HQIU) with Board staff. At the time investigators were moved to DCA, the Board identified the needed funding for the program at DCA. The budget was estimated at approximately \$15,498,000, but it has since increased to \$19,528,000.

Ms. Kirchmeyer elaborated that HQIU had a surplus of \$1 million in the last fiscal year due to vacancies. She noted that the level of spending is uncertain this year, since reports are not yet available. The adjustments made in 17/18 are ongoing and totals \$2.4 million for HQIU. Ms. Kirchmeyer noted that as a result of the increase, there may be a fee increase in the near future. Ms. Kirchmeyer mentioned that based upon information from DCA Budget Office the increases at HQIU are due to a 19% salary increase that employees at HQIU have received incrementally since 2016. The salary and benefit adjustments have impacted sworn investigators, medical consultants, office technicians, and all other staff.

Ms. Kirchmeyer mentioned that Ms. Nicholls discussed salary increases as a result of the Governor's budget release at the October Board meeting. She noted that an updated fund condition based on of these findings would be provided at the meeting in April.

Ms. Kirchmeyer explained the new system for voting on Board cases through the BreEZe system. All Members will be provided training. The Board's Information Systems Branch will provide the training.

Ms. Kirchmeyer remarked that, as previously stated, the Board might have to relocate to new offices in Sacramento. Information has been provided to the landlords and a meeting is set in February to discuss the terms. She commented that all staff has been informed.

Ms. Kirchmeyer explained that the Board will be working with the US Food and Drug Administration, (FDA), on a pilot program to provide notification to physicians about major public health issues. Through this program the Board will distribute important drug safety information to licensees on behalf of the FDA three to four times per year. Ms. Kirchmeyer detailed that the Board has done this for other state and federal entities. She added there is no significant effect on workload for the Board, and it is very helpful to enhance consumer protection.

Ms. Kirchmeyer announced that the Federation of State Medical Boards (FSMB) will hold their annual meeting in North Carolina in April. The Board is not allowed to travel to this state, but hopefully there will be an opportunity to attend via teleconference. Ms. Kirchmeyer noted that FSMB announced that the top important regulatory issues for state medical boards are telemedicine, opioid prescribing, physician stress and burn out, marijuana for medicinal purposes, and the interstate licensure compact.

Dr. GnanaDev commented that one of the reasons for the vacancies was the pay in HQIU. He noted that though the curve is steep, that is not the issue that is concerning. The most concerning is the timeframes, going from 310 in 2014-15 to 530 in 2017-18. For this reason he would like to see where the problems are, and then the Board can see what to do to fix them. Although he does understand that everything has a process, that is what legal structure is, the Board has the responsibility to get the times down for the sake of consumer protection. Dr. GnanaDev said the Board needs to analyze the process to see where the problems are and how they can be fixed. If it needs a legislative fix, it should be brought before the Board to discuss.

Ms. Kirchmeyer highlighted that the 7.44% increase that Ms. Nicholls has described will begin this year.

Dr. Lewis noted that there is a process that members of a bargaining unit need to follow due to contractual restrictions. He inquired if the Board should approach Senate Business, Professions, and Economic Development (B&P) Committee to receive more money.

Ms. Kirchmeyer added that what the chart is showing is that finally HQIU is starting to get money for the great work that they do. At the same time, this is what is impacting the Board's budget.

Dr. GnanaDev stated that discipline timelines need to be reduced to increase consumer protection.

Mr. Andrist mentioned that in compliance with Assembly Bill 1886 the Board has restored nearly 7,000 disciplinary documents. He asked how many documents are still missing and projected a timeline of when he thinks the Board will be done with this project. He stated that it is not public safety for the documents to be missing. Mr. Andrist compared the Board's website with his own website. He added with his website all documents, specifically withdrawals and public reprimands will remain forever.

# Agenda Item 7 Update on the FSMB Workgroup to Study Regenerative and Stem Cell Therapy Practices

Dr. Krauss explained that he was appointed to the FSMB work group to study regenerative and stem cell therapy practices. The issue is that some stem cell and regenerative therapy centers are placing consumers at risk by promoting, offering, and selling unproven, painful, or dangerous therapies. FSMB would like to find a solution to reform, limit, or close these centers without harming access to bona fide treatments or clinical trials.

Dr. Krauss added that the work group has a draft report, but there is not yet an official recommendation, until the study is discussed at the FSMB meeting in April. He provided a summary on the potential recommendations that the FSMB will be reviewing.

Dr. Krauss detailed that one recommendation will likely state that medical boards should raise awareness among licensees of applicable federal and state legislation and guidelines regarding regenerative and stem cell therapies, including right-to-try legislation existing or pending at the state and federal levels.

Dr. Krauss noted an additional recommendation, that state medical boards should also keep their licensees and the public apprised of new developments and regulations in the field of regenerative and stem cell therapies. This may include educational resources, guidance documents, and appropriate industry and stakeholder information on state board's websites.

Dr. Krauss added that state medical boards should further provide information as to reporting procedures of adverse reactions related to stem cell interventions.

Dr. Krauss explained an additional recommendation, that state medical boards examine their policies and rules addressing informed consent. He remarked that physicians should be prepared to support any claims made about benefits of treatments or device with documented evidence, for example with studies published in peer-reviewed publications.

Dr. Krauss noted that the work group found in numerous cases that were reviewed there is an inadequacy of informed consent. For this reason, it is vital that the work group reanalyze this issue. Another likely recommendation is to review professional marketing materials and claims. This will also include information publically available about an office, clinic, or licensee on online blogs or social media in relation to stem cell and regenerative therapies.

Dr. Krauss posed an additional proposed recommendation, that state medical boards proactively monitor warning letters sent by the FDA to practitioners, because there is a publically available FDA website that lists practitioners who have received such warnings. Dr. Krauss added that this will allow state boards to have greater insight and be able to actively pursue a licensee who may have received an FDA warning.

Dr. Krauss listed another likely recommendation is that where evidence is unavailable for a particular treatment, as in clinical trials or case studies, that physicians be admonished only to proceed when an appropriate rationale for the proposed treatment is justified; novel, experimental, or unproven interventions should only be proposed when traditional or accepted, proven treatment modalities have been exhausted.

Dr. Krauss continued onto another recommendation from FSMB, that physicians should refrain from charging excessive fees for the treatments provided. He added that he is personally aware of fees in the tens of thousands of dollars for unproven remedies. Further, physicians should not recommend, provide, or charge for unnecessary medical service, nor should they make intentional misrepresentations to increase the level of payment that they receive.

Dr. Krauss reemphasized that the final recommendations would not be final until the April FSMB meeting. He also noted that the FSMB is a body that offers recommendations. It is not a body that has any legislative or regulatory authority, but certainly the opportunity to participate in this workgroup is a great opportunity for the Board.

Dr. GnanaDev thanked Dr. Krauss for his work and confirmed the importance of the work since it offers benefits in consumer protection.

### Agenda Item 8 Presentation on the Report from the CURES Survey

Dr. Henry explained that his presentation was on the findings in a statewide survey of physicians and pharmacists. He stated the survey was a collaboration between UC Davis and the California Department of Public Health. This was done with coordination and additional help from the Board, State Board of Pharmacy, and the Osteopathic Medical Board of California.

Dr. Henry provided an overview of the presentation which included: a summary of the CURES 2.0 implementation, a review of the results from the survey that was conducted with focus on the physician response, and the potential implications for the mandatory CURES use law.

Dr. Henry detailed that the survey was conducted in order to elicit feedback on CURES 2.0 and the improvements to the CURES system. It was also intended to provide information to the Department of Justice (DOJ) for improving CURES and providing information to CURES users and stakeholders such as the Board, DCA, physicians, and pharmacists. An additional goal was to characterize CURES usage patterns, and effects on prescribing.

Dr. Henry added that the survey took place a couple of months after mandatory registration took effect, specifically in the Fall of 2016. Dr. Henry noted that the response rate was 22% for osteopathic and allopathic physicians. He noted that this was a good response rate given that it was a web-only survey. In the response 82% noted that they were registered for CURES.

Dr. Henry noted that there was some information that was given by the DOJ that tracks the estimate of CURES compliance registration. In terms of prescribers overall it is about 65%.

Dr. Henry explained that when asked why physicians were not registered, the most common response was that they did not know how to register and that there were other problems more important than registering for CURES.

Dr. Henry stated that when asked if CURES was helpful, 60% agreed or strongly agreed. He added that not many agreed that it was easy to use. There was 31% that felt that CURES was not relevant to their practice. Some portion of this number were physicians that were retired, but still had active licenses,

physicians who practice out of state, or physicians that have a DEA license, but generally did not prescribe controlled substances.

Dr. Henry explained that when asked how likely the physician thought that they would use CURES in the next three months, there was a wide range of responses.

Dr. Henry noted that when asked to compare the old version of CURES to the new version of CURES, the majority felt that it was the same. In addition, a large percentage felt that the new system was better and very few people opined that the system was worse.

Dr. Henry commented on areas of improvement. The majority of respondents had not heard of several of the most advanced features of the CURES 2.0 system. Items included the ability to send messages to other prescribers through the CURES, the capability to use delegates, or the ability to flag patients who have patient provider controlled substance agreements on file. He cited that less than 5% of the physicians had ever even used any of those features.

Dr. Henry added that physicians were also asked if when they checked CURES, what percent of the time did it alter their prescribing decision. The majority responded zero, ten, or twenty percent of the time. These findings suggest that there is a minority of the time when checking CURES that it does affect prescribing decisions for physicians.

Dr. Henry remarked that when asking the participants if they should check CURES before writing a controlled substance prescription, there was overwhelming support for this. Although when asked if it should be required, the number reversed and less participants were in favor. He pointed out the survey was sent out at the time that Governor Brown was signing the mandatory checking of CURES into law. He commented that the results found that the participants that took the survey after the law was in effect were much more favorable of the mandated requirement.

Dr. Henry mentioned that when asked if checking CURES fell into the standard of care, 38% of the respondents strongly agreed.

Dr. Henry discussed the implications of the survey. The first is that the effort to increase CURES use would be effective if the focus is on making CURES more useful and promoting CURES as normative among physicians. In addition, the law will increase CURES use among physicians.

Dr. Hawkins thanked Dr. Henry for his work and noted that as a practicing physician who uses CURES, he too finds CURES to be very helpful.

Dr. GnanaDev commented that he was amazed by the 8% of participants that did not know about CURES. He noted that although there are some issues, with the opioid epidemic there is no doubt that it is extremely useful.

Dr. Hawkins added that the more physicians use CURES, the easier it is to use CURES. In addition, CURES 2.0 has some shortcuts that are very helpful.

Dr. Henry noted that there are significant issues with IT integration and although he does not work for DOJ, he does know that they are working very hard to make it easier with AB 40 to integrate CURES into the medical record, but its seems like a slow process.

Dr. GnanaDev inquired how to find out if someone has a DEA.

Dr. Henry replied that this is public information. He noted that in the study about 9% of physicians did not have a DEA license.

Dr. Lewis asked if CURES might affect the opioid addiction problem, or if there are better tools to utilize.

Dr. Henry responded that in his experience CURES is a tool that provides another piece of information. He added that emergency medicine physicians view CURES as a way to limit drug seeking behavior. He stated that CURES is an essential tool for prescribing long-term opioids.

### Agenda Item 9 Update on the Physician Assistant Board

Ms. Forsyth began by announcing that Robert Sachs was elected president and Jed Grant was elected vice president at the Physician Assistant (PA) Board meeting. She noted that they are both practicing PAs in California and have invaluable knowledge.

Ms. Forsyth added the PA Board is currently averaging issuing between 20 to 30 licenses per week for new licensure. She noted that during graduation season, this number can be as high as 50 applications per week. Total there are a little over 11,000 licensed PAs in California and this number is expected to rise due to the opening of five new PA schools in the next few years.

Ms. Forsyth commented that the board completed an audit with the DCA Internal Audit Unit. The division spent three to four months in the PA Board office in order to understand procedures and processes relating to licensing and enforcement.

Ms. Forsyth mentioned that the PA Board is working on a number of regulations related to the PA practice. The PA Board is also in the process of seeking legislation to assist with a possible fee increase for the initial application, which is \$25 per application.

Ms. Forsyth stated that there are several schools currently going through the accreditation process and that the Keck School of Medicine at the University of Southern California is open, as well as another school in Southern California.

Dr. Yip mentioned that the medical school administration is adding education that will provide more information about substance abuse, medical ethics, and professionalism. This is taken as a preventative measure. He inquired if there is this emphasis in the PA programs.

Ms. Forsyth clarified that the school decides what curriculum they will provide. She added that the PA Board is extremely concerned with ethics.

# Agenda Item 10 Discussion and Public Action on Amending Title 16, California Code of Regulations, Section 1399.545

Ms. Forsyth noted that Senate Bill (SB) 337 required that any PA who transmits an oral order to identify the supervising physician, changed the medical record review provisions in order to require the supervising physician the utilization of one or more mechanisms, and changed provisions that specify how a PA documents controlled substances prescriptions. She stated that due to SB 337, amendments needed to be made to California Code of Regulations (CCR), Title 16, section 1399.545. The PA Board is requesting that the Board approve the proposed amendments and authorize staff to proceed with the rulemaking process.

Ms. Kirchmeyer explained that the law stipulates that the PA Board regulatory amendments, such as changes to the PA scope of practice, need to go through the Board. She added that the amendments presented by Ms. Forsyth have been approved by the PA Board and now need to be approved by the Board. She clarified that the proposed changes are to comply with the changes in SB 337. Ms. Kirchmeyer elaborated that PA Board staff and staff counsel will complete all the work on the regulation package and collaborate with the Board's staff counsel.

Dr. Krauss made a motion to approve the proposed amendments to 16 CCR Section 1399.545, to authorize staff to proceed through the rulemaking process, to notice the modified language for a 45-day comment period and hearing, upon DCA and agency approval, and to authorize staff to make any non-substantive changes to the proposed language during the rulemaking process; s/Dr. Lewis.

Ms. Webb noted that this work brings the regulation into compliance with the new language in Business and Professions (B&P) Code section 3502 and 3502.1.

Ms. Andres, Director of Government Relations for the California Academy of PAs (CAPA), thanked the staff of both the Medical Board and the PA Board for their work and noted that CAPA is supportive of the proposed language.

Motion carried unanimously (9-0).

## Agenda Item 11 Discussion and Possible Action on Legislation/Regulations

Ms. Simoes began by noting that the 2018 legislative session had started and that the bill introduction deadline is February 16, 2018. She continued to explain the tracker list. Additionally, she provided the Board with an update on the legislative proposals that were approved at the last Board meeting, specifically the University of California, Los Angeles (UCLA) international medical graduate proposal and the three omnibus proposals.

Ms. Simoes stated Board staff has approached Assembly Member Arambula's office for the UCLA international medical graduate proposal and he will author the bill that the Board is co-sponsoring with the UC Office of the President. She added the bill has not yet been introduced. She stated the three omnibus proposals were submitted to the Senate B&P Committee for inclusion in the committee's omnibus bill. Board staff has met with Senate B&P Committee staff and the proposals are going through the review process.

Ms. Simoes updated the Board on the 2018 Legislative Day. She noted that she will be working with Dr. GnanaDev and Ms. Pines on a timeframe for the next Legislative Day, potentially at the end of February or early March. Once a date has been decided, Ms. Simoes will reach out to all Board Members about participating. She commented that more details will follow, but it will be similar to the last Legislative Day, where Members will meet with Legislators that sit on the relevant policy committees to talk about Board issues.

Ms. Simoes transitioned to Assembly Bill (AB) 820 (Gipson). She explained that after amendments on January 3, 2018, the bill did not meet the deadline and therefore is no longer moving. However, the same language was moved into a new bill, AB 1795.

Ms. Simoes detailed the language, which would include the definition of advanced life support, which an emergency medical technician-paramedic (EMT-P) is authorized to provide, determining transport at the scene of an emergency to a community care facility or an acute care hospital. If transport to a community care facility is determined, the approved local emergency medical services (EMS) plan must be followed. She added that this language would define a community care facility as a mental health urgent care center or sobering center, which is staffed with medical personnel designated by a local EMS agency, as part of an approved local EMS plan. Ms. Simoes noted that this language would allow a local EMS agency to submit, as part of its EMS plan, a plan to transport patients to a community care facility that is not a general acute care hospital (GACH), based on a determination by an EMT-P that there is no need for emergency health care. This language has certain requirements and what the plan must include.

Ms. Simoes commented that this language would require the Emergency Medical Services Authority (EMSA) to authorize a local EMS agency to add to its scope of practice for an EMT-P those activities necessary for the assessment, treatment, and transport of a patient to a community care facility, upon approval of the EMS plan to transport the patient to a community care facility.

Ms. Simoes confirmed that Board staff consulted with a physician Board Member and provided input to Office of Statewide Health Planning and Development (OSHPD) on Health Workforce Pilot Project (HWPP) #173 in 2014. This language would authorize one of the original six concepts allowed for in the pilot project. She noted that one of the concerns raised by the Board was related to the transport of a patient to an alternate location other than a general acute care hospital emergency department (GACH ED). At that time, the Board was concerned that transport of a patient to an alternate location other than a GACH ED carries the risk of a patient being transported to a facility that is not appropriate to meet the patient's needs, especially in cases where presenting signs and symptoms of life-threatening illnesses may be subtle. Ms. Simoes stated that in such cases the Board stated in its letter that failure to have transported that patient to a GACH ED may jeopardize that patient's well-being and survival. She added that Board staff think that this concern is still relevant to this bill, and therefore Board staff recommended that the Board take an oppose position on this bill.

Dr. Krauss noted that if the bill's language is appropriately restrictive, the Board may need to reconsider its previous position. He said that with certain stipulations, he believes that the bill may be a good thing and would provide benefits to consumers. Dr. Krauss noted that before full endorsement, he would need to obtain more information about acute mental health care centers and sobering centers.

Dr. GnanaDev agreed with Dr. Krauss, but clarified that he would like to ensure proper amendments are made for consumer protection. He noted that there needs to be approval from the base station rather than a paramedic making a decision in order to preserve consumer safety.

Dr. Krauss concurred with Dr. GnanaDev's concern and expressed that the Board take a neutral if amended position.

Ms. Simoes clarified the requirements for the EMS plan does require the local EMS agency have criteria for designated facilities and must include appropriate medical staffing and administrative medical oversight.

Ms. Kirchmeyer added that the language in the bill limits community care facilities to the two specified centers, an acute mental health care center or a sobering center.

Dr. Lewis stated that if there are enough restrictions and strong communication between the base station doctor and the paramedic it might be plausible. Although prior to making a decision, he requested to hear from representatives who have done research on this issue and requested that information be presented at the April Board meeting.

Dr. Krauss noted that paramedics are already trusted to make clinical decisions and for this reason, if the guidelines are restrictive and there is quality of medical screening, the bill could be acceptable.

Dr. GnanaDev added his concerns about safety and elaborated that he would like to ensure the involvement of the base station physician. He reiterated that there are issues with the bill, but that it does have good points and before taking an official stance, the Board needs to ensure consumer safety.

Ms. Bartleson, California Hospital Association (CHA), remarked that CHA is concerned about the quality of safe patient care. She added that CHA has worked very closely with EMSA, OSHPD, and the local EMS agencies. However, emergency care systems are in a state of peril and the demand cannot be contained. She elaborated on the amount of patients seen and the types of cases treated. She stated that emergency departments are at a breaking point and for this reason, CHA strongly asks for the support of the Board on this bill.

Mr. Madden, California Chapter, American College of Emergency Physicians (CACEP), explained that his organization has been involved in the discussion around the pilot programs for the last three years. He remarked that his organization has taken an oppose unless amended position, since there are patient safety concerns. He concurred with the worries of the Board Members that the paramedic not identify an acute situation and inappropriately transfer, which would be a detriment to patient safety. He added that if the amendments are conducive to safety, his organization would be open to changing their stance.

Mr. Madden continued into the language in the bill that is concerning. He began by noting that this bill would greatly expand the scope of practice for paramedics. As it stands right now, the role of a paramedic is to assess the patient and transport to the hospital. Mr. Madden stated that if the question is whether or not the patient should be going to a sobering center or a behavioral health center, this bill goes beyond that by specifically stating that they are in a position to be treating the patient. This is not further defined within the legislation.

Mr. Madden continued that the bill is limited to behavioral health centers and to sobering centers. He noted that the challenge there, specifically with sobering centers, is that there is no facility type defined or regulated in California that is a sobering center. Similar to an outpatient surgery center, which is

subject to accreditation requirements, there is no similar structure for a sobering center. Mr. Madden added that there is some language that the local EMS might come up with some regulations as it might relate to it, but this is different from accreditation. He noted that this would need to be defined within the legislation, which is a huge undertaking.

Dr. GnanaDev added that there are a lot of amendments which need to be in the bill before a position is taken.

Dr. Miller, Santa Clara County EMS Agency and a principal investigator for the Santa Clara County EMS Mental Health and Sobering Center Altered Destinations Pilot Project, noted that AB 820 has been replaced by AB 1795 and amends the Health and Safety Code to define the community care facilities as mental health urgent care and sobering centers. This is a narrower scope than prior legislation. It also authorizes medical directors of local EMS agencies to include in their EMS plans paramedic scope of practice and transport destination policies to include community care facilities.

Dr. Miller noted that the issues that have been raised regarding community paramedicine and mobile integrated health care in California include local EMS medical director's determination of patient transportation destinations, as well as patient safety. He added that regarding the EMS determination of patient transportation destinations, it has been an evidence-based practice for more than 30 years for trauma and most recently for stroke, burns, and obstetrics to name a few. Dr. Miller detailed that in regard to patient safety the health care workforce pilot projects have medical directors that are certified in emergency medicine and have quality assurance officers. The community paramedics have real-time access to physicians and registered nurses for consultation. Electronic pre-hospital patient care systems can provide real-time notification of project investigators and managers when patients are enrolled in the study and provide data monitoring, trending, and analysis on a patient-by-patient basis.

Dr. Miller explained that evidence-based inclusion and exclusion criteria are part of the institutional review board approved pilot projects. Each pilot project has a local steering committee, with both subject matter experts, EMS, health care stakeholders, and a member of the public who is not affiliated with the project. At the state level there is a statewide steering committee that reviews data quarterly and an independent evaluator that reviews pilot site data. He added that pilot site protocols are reviewed by the EMSA and OSHPD. Dr. Miller added that all unusual occurrences are reported to EMSA's pilot project manager.

Dr. Miller continued that this pilot project he is working on transports patients to licensed psychiatric facilities and to medically supervised sobering centers. Behavioral crisis, psychiatric disorders and substance abuse disorders are common among 9-1-1 EMS patient encounters. There is a need for enabling legislation to further advance the practice of community paramedicine and mobile integrated health care in California. Dr. Miller confirmed that these programs have the potential to increase access to specific health care patients and to provide means to evaluate efficiencies and economies of health care that is more customized through pre-hospital care systems.

Dr. Kazan, Los Angeles County Fire Department, noted that he has been a practicing emergency physician in Southern Los Angeles for the past 12 years and is the current full-time medical director for the Los Angeles County Fire Department. He noted that at LA County Fire, they see about a 1,000 patients a day, which makes them as busy, or busier than any ED in the state.

Dr. Kazan detailed that LA County Fire is in a crisis. The ED systems are unsustainable. He noted that people are unwilling to accept the fact that the ED functions at or near capacity on a regular basis. He remarked that as much as there is talk about the flu epidemic being such a terrible thing, the flu epidemic is entirely predictable since it is annual. While some years may be a little worse than others, it is an entirely predictable phenomena and yet it completely overwhelms the ED.

Dr. Kazan stated that he has reviewed the Board's legislative analysis for AB 820 and nowhere in the analysis does it say that the paramedics that are out in the field are practicing under the supervision of their medical director and that the medical director practices under the regulatory supervision of another EMS physician. He clarified that paramedics are not out in the field operating independently. All paramedics are trained to operate within a system of care that is established as EMS physicians.

Dr. Kazan noted that best practice is continually performed. Paramedics are trained in triage. The trauma system is a great example by which paramedics assess and treat trauma patients in the field and transport them to an appropriate center. There has been a safety net system that has been developed so when patients are under triaged and they go to a non-trauma center, there is a system to rescue those patients and bring them back into the trauma system. Dr. Kazan commented that there is no reason to think that a similar system would not be created for mental health patients or patients that are in need of a sobering center.

Dr. Kazan concluded by noting that those that are opposing the bill have no suggestions. He remarked that maintaining the status quo is unacceptable.

Ms. Allred, California Medical Association (CMA), noted that the CMA supports maintaining an oppose position on this bill due to the many safety concerns.

Dr. Yeh noted that he thought that the Members of the Board hit many of the key issues. Dr. Yeh is an emergency physician at San Francisco General Hospital as well as faculty at the University of California, San Francisco. In addition he serves as the medical director for the fire department.

Dr. Yeh mentioned that the sobering center has been in operation since 2003. The model for this is very similar to the concept of STEMI centers, trauma centers, and other focused specialty care centers. The paramedics do a thorough evaluation and have a checklist protocol to determine if a client is appropriate to be transported to a sobering center. In addition, there is a nurse on-duty 24 hours a day who performs intake assessments. He noted that the actual rate of clients who need secondary transport to an ED for further care is very low, around 4%. Dr. Yeh would argue that this is an enhancement upon the standard care that is attempted to be done in a system that is not geared to dealing with chronic behavioral disorders or substance abuse.

Dr. Yeh added that the positive effects of the program have been published in many peer-reviewed journals, but beyond the data, it improved the lives of many people. He applauded the Board's interest and diligence in this matter. He has found that the sobering centers have been a very important resource for the care of vulnerable people in his city. Dr. Yeh strongly encourages the Board to support improved access to community care facilities.

Ms. Kim, California Nurses Association (CNA), noted that CNA opposes the bill because it threatens patient safety by authorizing the use of paramedics to provide health care services that are currently

provided by physicians, registered nurses, and social workers. There are pilot projects that allow paramedics to provide care that is not currently authorized by law and as part of the project, paramedics are undertaking care currently performed by physicians, registered nurses, and social workers. Paramedics have limited additional training, which is not nearly enough for them to acquire the level of expertise and skill needed to ensure patient safety. Ms. Kim commented that in the case of the sobering center pilot project, paramedics only received eight hours of additional training.

Ms. Kim noted that the patient population that has been enrolled in the pilot project does not reflect California's diverse population with the exception of two projects. The first year data shows the overwhelming majority of those enrolled in pilot projects were disproportionally English speaking, white males. In addition, during the review of the project, most of the data collection is focused on cost savings and not patient outcomes. Ms. Kim commented that CNA believes the end result will be cost savings for hospitals and health insurance and a lower standard of care for the most vulnerable people in society.

Ms. Kim remarked that there is no tracking of the number of patients brought to the sobering center pilot site, but refused admission by the center staff. Those numbers are important since they could be an indication that the paramedic made the wrong decision in deciding to divert a patient to the sobering center, rather than bringing the patient directly to the ED.

Ms. Kim stated that references have been made to the University of California, San Francisco (UCSF) evaluation of the pilot program. CNA has completed their own review of the data used by the health force center at UCSF and found the evaluation incomplete and inaccurate in a number of ways. She noted that there were a significant number of patients enrolled in the pilot project to return to the ED after discharge from the hospital.

Ms. Kim concluded by noting that CNA opposes the bill, since the bill would expand the scope of practice for paramedics and increase industry profits at the expense of public safety and public health.

Dr. Stock spoke on behalf of the board of directors of CACEP and remarked that the bill is about expanding the scope of practice for paramedics in California. The population that is being looked at, the 9-1-1 callers, is not a low-risk population. He added that patients with behavioral health problems and alcoholism have multiple other medical problems, housing challenges, and other issues. For this reason they are a complex group of patients.

Dr. Stock inquired where there is evidence that a community paramedic could make the key decisions of whether the patient goes to the hospital or not. He remarked that there is evidence in the literature that supports that up to 20% of patients are under triaged, meaning that a paramedic in a study felt that the patient was not sick enough to go to the hospital. Dr. Stock noted that in the current system the patient has never heard of a paramedic under triaged system because they at least go to the hospital where there is an emergency physician and an emergency care team. Another alternative is that they go to a higher level of care. He commented that going to a sobering center or a behavioral health center, which does not necessarily have a physician on-site for any part of the patient's visit, is not the same; it is a lower level of care.

Dr. Stock noted that CACEP is working with Dr. Mackey to try and collaborate. Currently Dr. Mackey is trying to determine best practices and when those are determined, trying to replicate those throughout California would be the proper language to use. There was also a meeting with Dr. Hill, Dr. Kazan, and

Dr. Katz trying to seek an opportunity to collaborate. CACEP is taking an oppose unless amended position.

Dr. Gausche-Hill, medical director for Los Angeles County EMS, added that currently paramedics are involved in triage of a large number of medical complaints and are subject to multiple levels of quality review. The proposed bill requires policies and procedures in place to evaluate the patients in the field, but to also triage these patients at sobering centers, which includes evaluation by nurses and oversight by a medical director.

Dr. Gausche-Hill believes that this an important opportunity for the state of California and paramedics. She added that this is something that paramedics already do for many other more serious complaints.

Dr. Krauss commented that he thinks that the bill is not fully developed and that the Board will need more information. He understands that there is an extended ability in paramedics being able to make a triage decision, but the bill also speaks about their ability to treat.

Ms. Simoes clarified that the bill states the language requires EMSA to authorize a local EMS agency to add to its scope of practice for an EMT paramedic those activities necessary for the assessment, treatment, and transport of a patient to a community care facility upon approval of a plan.

Dr. Krauss added that he is a bit uninformed as to what the adequacy is of the local mental health acute care centers and sobering centers. He stated that without there being a requirement of state or national accreditation that there is probably quite a variation in terms of the adequacy of the facility and the medical staffing of those centers. Dr. Krauss stated that he would like the bill to be amended to actually specify criteria since there is no accrediting agency for consumer protection.

Dr. Krauss noted that he likes the concept of the bill, since EDs are overburdened and patients would be able to receive better care if they are sent to appropriate care centers.

## Dr. Krauss made a motion to support the bill, if amended. Dr. Krauss modified his motion to support in concept; s/Dr. Lewis.

Dr. GnanaDev reiterated that the Board would like several amendments, including: patient protection, no expansion of the paramedic scope of practice, and supervision by the base station physicians or whomever else supervises them.

Ms. Kirchmeyer added that Dr. Krauss would like the criteria to be specified in the bill.

#### Motion carried unanimously (9-0).

Ms. Simoes introduced AB 1751 (Low), which would allow the DOJ to enter into an agreement with an entity operating an interstate data sharing hub for purposes of participating in inter-jurisdictional information sharing between prescription drug monitoring programs across state lines. She noted that this would allow CURES to interact with other state prescription drug monitoring programs. The Board believes CURES is a very important enforcement tool and an effective aid for physicians to use to prevent doctor shopping. Ms. Simoes remarked that this bill will give physicians access to prescription

drug information in other states, which will help to further the Board's mission of consumer protection. She stated Board staff recommended the Board support this bill.

### Dr. Lewis made a motion to support AB 1751; s/Ms. Pines. Motion carried unanimously (9-0).

Ms. Simoes explained AB 1752 (Low), which would add Schedule V drugs to CURES and would authorize the California State Board of Pharmacy (BOP) to add additional medications to CURES through regulations if a medication is determined to pose a substantial risk of abuse or diversion. This bill would also shorten the timeframe for pharmacists to report dispensed controlled substances to CURES, from the current seven days, to one working day after the date a controlled substance is dispensed.

Ms. Simoes added that this bill will not add Schedule V drugs to the section of law that requires physicians to check the CURES database. Therefore, adding Schedule V drugs to CURES will have a significant impact on dispensers, not prescribers. She noted that changing the reporting deadline for dispensers will result in more up-to-date information in CURES and will make it even more of an effective aid for physicians to use to prevent doctor shopping. She added the Board may want to discuss and consider the language that would authorize the BOP to add additional medications to CURES through regulations if a medication is determined to pose a risk of abuse or diversion.

Dr. GnanaDev questioned why the BOP is trying to get cough syrup with codeine listed as a Schedule V drug.

Ms. Simoes remarked that she and Ms. Kirchmeyer spoke with the BOP and it was noted that there are some circumstances where cough syrup is being inappropriately prescribed and used with other scheduled drugs, which is becoming an issue.

Ms. Kirchmeyer stated that cough syrup is currently being abused. She mentioned that there have been cases where promethazine with codeine is being provided to patients outside the standard of care. She stated it is for consumer protection to have it in the database. She added that doctors will be able to see it in CURES, and check it for their patients.

Dr. Lewis remarked that since you need to show identification at the time of purchase, he does not think that there needs to be additional steps. It is putting more on the physicians.

Ms. Kirchmeyer noted that entering the information would be on the pharmacist, not the physician, unless direct dispensing.

Ms. Simoes mentioned that the BOP would have to go through the regulatory process for any new drugs, but the BOP could add other medications if they pose a risk for diversion.

Dr. Bholat stated that promethazine with codeine is diverted not infrequently and is quite rampant in the homeless population in Los Angeles. She agreed that she shares the concerns and noted that if physicians would be required to check for Schedule Vs, this is something that she would oppose. Although she would be in favor of Schedule Vs appearing in CURES since it would allow her to see how many places a patient is going to get medication when she checks CURES.

Dr. Hawkins added that he fully agrees with Dr. Bholat and has witnessed this abuse in his practice.

Ms. Kirchmeyer added that quite a number of facilities are already entering Schedule Vs into CURES. Dr. Lewis made a motion to support AB 1752 if amended to remove BOP's authority to add drugs to those required to be entered into CURES; s/Dr. Bholat.

### Motion carried unanimously (9-0).

Ms. Simoes explained AB 1753 (Low), which would require DOJ, beginning January 1, 2020, to limit the number of approved security printers to three. Currently there are security printers in DOJ and all the prescription pads have to be printed by these printers. The bill would also require specific information be on the forms. The Board staff has received complaints that medications have not been filled since prescriptions are on non-compliant forms. Ms. Simoes remarked that this bill does not directly impact the Board, but because Board staff has seen an issue with this, the bill is being mentioned.

Dr. Bholat echoed the concern of patients not being able to pick up prescriptions. She also inquired more about the limit of three printers.

Ms. Simoes answered that currently there are more than three printers and sometimes prescriptions that are being printed are non-compliant. For this reason, the purpose would be to have three approved security printers with new serial numbers to avoid compliance issues.

Dr. GnanaDev asked how this would affect the electronic transmission of prescriptions.

Ms. Simoes confirmed that the printers do not affect electronic transmission, it only pertains to printed prescriptions.

Ms. Kirchmeyer commented that this bill is not expected to impact physicians. It might, however, if a physician is having trouble with non-compliant prescription pads.

The Board agreed to not take a position, but to watch this bill.

Dr. GnanaDev noted that he had a speaker slip for AB 1650.

Ms. Simoes noted that AB 1650 is a two-year bill that the Board has already taken a position on and this is why the Board would not be discussing it.

Mr. Klug, a registered nurse and integrated health manager for Medic Ambulance Service in Vallejo, noted that he has been managing the daily operations of the Vallejo clinical site, which is a post discharge model. He added that he works with heart failure or chronic obstructive pulmonary disease patients. His site has seen patients for two and a half years with tremendous results. They have an unplanned readmission rate over a 30-day period of 6.9%, which is a 58.9% reduction compared to the eligible but not enrolled patient population.

Mr. Klug confirmed that his site is not a duplication of services, rather they fill the gap in care by working with the local hospitals who refer patients to them. The site maintains the compliance and reinforces the education of their post-discharge plan. This is done by completing a medication inventory

analysis, which is then shared with the referring hospital, the patient's primary care doctor, and any other specialists as needed. The instructions are reviewed with the patient and they reinforce the medical plan provided. Mr. Klug noted that thus far they have found a 53.1% rate of medication errors and 73.8% discrepancy rate in discharge instructions. He confirmed that the site is not trying to change the plans, rather they are there to reinforce the instructions.

Mr. Klug added that there has been a 78.1% rate in the reduction of readmission for heart failure or chronic obstructive pulmonary disease patients. For this reason, he asks that the Board reconsider the opposed stance on AB 1650.

## Dr. GnanaDev adjourned the meeting at 5:52 p.m.

#### **RECESS**

Friday, January 19, 2018

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

#### **Members Present:**

Dev GnanaDev, M.D., President Michelle Anne Bholat, M.D. Randy W. Hawkins, M.D. Howard R. Krauss, M.D. Ronald H. Lewis, M.D., Secretary Denise Pines, Vice President David Warmoth Jamie Wright, J.D. Felix C. Yip, M.D.

#### **Members Absent:**

Kristina D. Lawson, J.D. Sharon Levine, M.D. 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
Regina Rao, Associate Governmental Program Analyst
Letitia Robinson, Research Program Specialist II
Elizabeth Rojas, Staff Services Analyst
Jennifer Saucedo, Staff Services Analyst
Jennifer Simoes, Chief of Legislation
Lisa Toof, Staff Services Manager I

Carlos Villatoro, Public Information Manager Kerrie Webb, Staff Counsel

#### **Members of the Audience:**

Lynne Andres, California Academy of Physician Assistants

Eric Andrist, via phone

Andrew Armenta, via phone

Noryln Asprec, Executive Director, Health Professions Education Foundation

Gloria Castro, Senior Assistant Attorney General, Health Quality Enforcement Section (HQES), Attorney General's Office (AGO)

David Chriss, Chief, Division of Investigation, Department of Consumer Affairs (DCA)

Zennie Coughlin, Kaiser Permanente

Claudia Crist, Deputy Director, California Department of Public Health

Rosanna Davis, L.M., California Association of Licensed Midwives

Louis Galino, Videographer, DCA

Shalena Garza, M.D., via phone

Andrew Hegelein, Northern Area Commander, Health Quality Investigation Unit (HQIU), DCA

Marian Hollingsworth, via phone

Susan Lauren, via phone

Patrick Le, Assistant Deputy Director, Board and Bureau Services, DCA

Craig Leader, Investigator, HQIU, DCA

James Lin, M.D., The Permanente Group, via phone

Machaela Mingardi, Deputy Attorney General, HQES, AGO

Michelle Monseratt-Ramos, Consumers Union Safe Patient Project, via phone

Kathleen Nicholls, Deputy Chief, HQIU, DCA

Rose Neilan, via phone

Mark Scarlett, Supervising Investigator, HQIU, DCA

Anastasia Swartz, Special Investigator, HQIU, DCA

Mary Cain Simon, Supervising Deputy Attorney General, HQES, AGO

Tim Smick

**Tammy Smick** 

Carrie Sparrevohn, Licensed Midwife, Midwifery Advisory Council

Brentston Taylor, Special Investigator, HQIU, DCA

Kayla Watson, Center for Public Interest Law

### Agenda Item 12 Call to Order/Roll Call/Establishment of a Quorum

Dr. GnanaDev called the meeting of the Medical Board of California (Board) to order on January 19, 2018, at 9:12 a.m. A quorum was present and due notice was provided to all interested parties.

#### Agenda Item 13 Public Comments on Items not on the Agenda

Ms. Smick recited the mission of the Board, and noted that in the case against Dr. Daniel J. Headrick the Board failed miserably. She added that the Board's website states that death cases are given priority, but in the case of her complaint it took more than four years to reach a resolution.

Ms. Smick detailed that her son, Alex Smick, went to Dr. Headrick's facility to safely detox from prescription pain medications. Two hours after arriving to the facility, Alex was started on a lethal combination of medications. Dr. Hedrick wrote an order to check on Alex's vitals only while awake and Alex was left unmonitored for over seven hours. Ms. Smick added that when he was checked on during morning rounds, Alex was deceased.

Ms. Smick added that nearly three years after the complaint was filed an accusation was filed against Dr. Headrick for repeated negligent acts. Ms. Smick detailed that on December 21, 2017, she received an email from the Board noting that a decision had been reached and after reading a 16 page legal document she realized that Dr. Headrick received a public letter of reprimand.

Ms. Smick inquired how the Board could let a doctor who was accused of overmedicating a patient get away with a slap on the wrist. She added that the job of the Board is to protect the public not protect dangerous doctors.

Ms. Smick explained that 42 years ago the Governor signed MICRA, the cap on pain and suffering damages, into law with the promise that the Board would be there to protect the public. With the existence of MICRA, the Board has an extra duty to protect the public.

Mr. Smick stated that they entrusted Dr. Headrick with their son, Alex, and his negligent acts killed their son. Mr. Smick shared how he is appalled with the Board's handling of the complaint. He trusted the Board to do the right thing, and the Board failed him.

Mr. Smick explained that they went to the police and were referred to the Board. They then filed a lawsuit, but their access to justice was blocked by MICRA. Mr. Smick commented that for more than four years they waited for the Board to take action against Dr. Headrick, but he got nothing more than a public letter of reprimand.

Mr. Smick inquired where the accountability and the incentive to change are. He noted that Dr. Headrick is not deterred by any California law and because of that patients continue to be put at risk. His future patients will likely never know what he did. There was a chance to stop him, but the Board did not.

Dr. GnanaDev noted that if they would like more details, Board staff can be reached. He added that there are two panels, each panel evaluates the case, and comes to a decision. It is a very thorough process and the cases are largely determined by the expert opinion. Dr. GnanaDev added that it is up to the expert reviewer to determine if the quality of care was met, or was lacking. He explained that more than anything else the Board would like to make sure that no patient is harmed.

Ms. Lauren requested that her case be reopened and the license of the surgeon that severely mutilated her be permanently revoked in the interest of public safety. She continued, that the Board experts need to be replaced. She added that she was medically recommended for breast reduction as a solution for pain, not for weight loss since she was healthy and muscular and worked out daily. Ms. Lauren continued, that the board-certified plastic surgeon that was

recommended to her by her primary care physician destroyed her breasts and used power assisted liposuction, which was something that she did not approve.

Ms. Lauren noted that the surgeon's records are inept and fabricated. She detailed that his wife is his office manager and that there are no checks and balances and his office is not accredited. Ms. Lauren noted that this surgeon should be revoked based on the original complaint and that she was not satisfied with the way that her case had been handled. Litigation is used to antagonize victim blame and to slander her. Ms. Lauren commented that the surgeon's attorney assassinated her character with lies and tried to silence her with a gag clause.

Ms. Lauren concluded, that the Board should do the right thing for public safety and permanently revoke the license of the surgeon that mutilated her, committed fraud, staged a criminal cover-up, and showed no remorse. Those who deny this are responsible for harm to future patients and give dangerous carte blanche to the surgeons.

Ms. Neilan commented that 11 year ago she went in for a slight breast reduction and felt pressured into having liposuction. She went to a board certified surgeon, who took a conservative amount of fat from her breasts and abdomen. She added the long-term negative effects are still with her and will last a lifetime.

Ms. Neilan explained that as a registered nurse and fierce researcher, she has concluded that fat removal is harmful for many reasons, one being fat redistribution, the other being that fat is an organ. She concluded that liposuction is a harmful procedure that does the opposite of its claim and may even shorten the human lifespan.

Mr. Andrist thanked the victims of the Board that are in the audience and watching on the telecast, in addition to members of the press who are tuning in to hear how the disciplinary guidelines work.

Mr. Andrist noted that in 2004 Dr. Marvin Derek failed to drain a massive pericardial effusion, which resulted in the death of the patient. In 2007, he left a surgical sponge inside a patient and in 2008, he left two surgical sponges in another patient. In the accusation it is written that respondents' failure to confirm the final sponge counts prior to wound closure in these two surgeries and the failure to dictate notes confirming that the final counts were correct, constitute repeat acts of negligence by respondent. Mr. Andrist continued, his failure to drain the massive pericardial effusion constitutes gross negligence and an extreme departure to the standard of care. Despite all this, this surgeon received a public letter of reprimand with the unusual stipulation that he was to retire within ten days. The surgeon signed and agreed to this, but he still has his California license and is practicing in Decatur, Illinois.

Mr. Andrist expressed his interest in hearing more in the disciplinary guidelines presentation to understand about uniformity, consistency, and fairness, since the case of this surgeon does not demonstrate this. He noted that the public is amassing a huge treasure trove of these cases that prove the Board is not doing its job to protect the citizens of the state from bad doctors. Mr. Andrist provided four more examples of complaints. He added that the Board's disciplinary rate is unacceptable and more people are stepping up every day to say that they will not stand for it any longer. Mr. Andrist commented that soon he will call for an audit of the Board.

# Agenda Item 14 Presentation on the Steven M. Thompson Physician Corps Loan Repayment Program

Ms. Asprec, Executive Director of the Health Professions Education Foundation (HPEF), provided information on the Stephen M. Thompson Corps Loan Repayment Program. She provided an overview and noted the mission of the HPEF. She also provided information on the HPEF programs, award criteria, and awardee obligations. Ms. Asprec detailed how Stephen M. Thompson Loan Repayment Program works, the application cycles, and how it is funded.

Ms. Wright questioned, since HPEF is housed within the state, what type of fundraising does HPEF do and if there are restrictions. She also asked for more information about the outreach programs.

Ms. Asprec answered that HPEF is uniquely situated under the state, but it has 501(c)(3) status, which gives it the flexibility to obtain grants and donations. In regard to outreach, they are active in their partnership with University of Southern California medical school, as well as the UC medical schools. HPEF has reached out to all of the deans to promote the Stephen M. Thompson Loan Repayment Program and they are active in going to health professional fairs.

Dr. Krauss commented that the Stephen M. Thompson Loan Repayment Program has been an avenue to improve the availability of care in underserved communities. He noted that the Board has been active in supporting this fund and was active in the administration. The Board has mentioned the Fund in the Newsletter, and will continue to do this. Dr. Krauss concluded that anything the Board can do to help get the word out, they would do since the program helps underserved populations.

Dr. Yip noted that the federal qualified health centers qualify and asked if an applicant who is in Los Angeles County would qualify for the program.

Ms. Asprec confirmed that they would.

## Agenda Item 15 Discussion and Possible Action on Appointment of Two Members to the Health Professions Education Foundation

Dr. GnanaDev stated that based upon Member interest in the HPEF, it is the recommendation that Ms. Lawson and Ms. Sutton-Wills be appointed to the HPEF as the two Members from the Board for two years. If others are interested in being on the HPEF, there will be an opportunity at the end of that period. Dr. Gnanadev requested a motion to appoint Ms. Lawson and Ms. Sutton-Wills to the HPEF.

Dr. Lewis made a motion to approve the appointment of Ms. Lawson and Ms. Sutton-Wills to the HPEF; s/Dr. Yip. Motion carried unanimously (9-0).

# Agenda Item 16 Presentation and Discussion on the Disciplinary Guidelines and the Board Member's Role in the Disciplinary Process

Ms. Webb provided a presentation on the disciplinary guidelines and a suggested approach to reviewing cases. She noted that the Board's priority is consumer protection and that the goal of discipline is consumer protection, not punishment. She stated that the protection of the public is the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Ms. Webb made the distinction that when protection of the public is inconsistent with other interests sought to be promoted, the protection of the public is paramount.

Ms. Webb provided an overview of the purpose of the disciplinary guidelines as well as the history. The disciplinary guidelines are to assist the Board in evaluating cases, help foster uniformity, consistency, and fairness, and act as a deterrence. She clarified the differences between proposed decisions and stipulations. Specifically, a proposed decision is written by an administrative law judge after an administrative hearing, and a stipulation is an agreement reached between the parties after settlement negotiations, prior to a hearing, and often involves input from the administrative law judge. The presentation offered suggested ways to review a proposed decision and a stipulation as well as provided two fictitious examples. One way in which a proposed decision is different from a stipulation is that a proposed decision results from a full administrative evidentiary hearing. Ms. Webb commented that a stipulation is a proposed settlement between the parties designed to avoid the delay and uncertainty of going to hearing. She commented that the role of a stipulation through settlement is that when the terms provide sufficient consumer protection, the Board is able to get the licensee disciplined, monitored, rehabilitated sooner without the delay and uncertainty of a hearing. Ms. Webb explained factors that may warrant deviation from the guidelines. These factors include mitigation, witness availability, witness credibility, expert credibility, age of the violation, and the level of certainty that discipline will be obtained at hearing.

Dr. Lewis asked about writs, possible outcomes, and the advantages or disadvantages to the respondent or the Board to filing a writ.

Ms. Webb answered that a physician that has been disciplined by the Board can file a writ with the Superior Court to challenge that discipline and the basis therefore. She noted that the Superior Court judge may strike causes of action that the Board has relied on to impose the discipline. Ms. Webb provided an example of this. She noted that these changes add to the delay of imposition of discipline and the decision may be stayed during that time, in which case, monitoring is not occurring.

Dr. Lewis noted that this might take a long time.

Ms. Webb confirmed that it can. She added that these cases are given priority on the court's calendar at least initially, especially if the physician is asking for a stay of the Board's decision. Once it is determined whether the stay will be imposed, if there are further hearings required, often this can take many months and sometimes years.

Dr. Yip inquired about the avenue of appeal for an unsatisfied consumer. He was wondering if the consumer files a complaint with the Board, or if there is an internal system.

Ms. Webb answered that they are filed internally with the Board. She added that consumers can ask to have the matter revisited when they receive their closure letter and can present new evidence.

Ms. Kirchmeyer added that a complaint received by the Board is a complaint of the Board. She noted that individuals may be interviewed during the process, but at the end of the day, it is the Board's decision. She added that there are two different pathways, there is the administrative action against the physician's license, which is the Board's complaint, and there is a civil action, which is the consumer's personal case against the physician, allowing consumer input.

Ms. Webb noted that the Board's process is similar to criminal cases, where it is the people of the State of California versus a defendant and it is not the individual victim's case. She added that it is heart wrenching and very disturbing when it does not go the way the victim wants, but the District Attorney takes that case on, on behalf of the State of California.

Dr. Krauss noted that a struggle has been the long timelines. He recommended that Ms. Webb and Ms. Kirchmeyer emphasize the process to consumers in order for them to understand what is and is not within the control of the Board. Dr. Krauss inquired what aspects are not under the control of the Board.

Ms. Webb replied that the investigations are done through DCA, HQIU. The administrative law judges are under the authority of the Office of Administrative Hearings and they set the hearing dates. She noted that some physicians or the attorneys may ask for continuances of the hearing, which delays the process every step along the way, and the Board is not in control of this. Ms. Webb added that even before this, getting the medical records can sometimes take time and if there are challenges, it might require the subpoena enforcement process, which can take many months to get through, since it is through the civil court.

Ms. Kirchmeyer added that the prosecution of the case is also outside of the Board. This is done with the AG's Office. She noted that the Board does the upfront complaint part and the final review process to get it to the panel to vote, and what happens in between is dependent on other entities.

Ms. Smick noted that if the Board was really following the disciplinary guidelines she would not be at the meeting. She noted that on slide one it states that the public protection is paramount and in her case against Dr. Headrick, the public was not protected. She added that the purpose of disciplinary guidelines is to act as a deterrent, but the public letter of reprimand that was given to Dr. Headrick will not deter him from his dangerous practice. Ms. Smick noted that a slide states that a stipulation is a proposed settlement between the parties designed to avoid the delay, but her case took over four years. She waited for the Board to take action, and when they did, it was unacceptable.

Ms. Smick commented that in the case of Dr. Headrick there is no rehabilitation. He can continue to practice as he has been practicing since the Board did not require him to take classes to learn

about the dangerous drug medications that he gave, or monitoring patients. She stated that in her case there was not sufficient discipline, rehabilitation, and it was not closed in a timely manner. For this reason she came to confront and expose the Board and she vowed to not stop fighting to change the Board so that consumer protection is paramount.

Ms. Wright stated that she has been on the Board since 2013 and she has listened to the feedback that the Board gets from members of the public. She noted that she is a public member. Sometimes there is the perception that it is doctors protecting other doctors. She commented that she is harsh on the DAGs and the doctors that come before Panel A. Besides being a member of the public, she is also a lawyer and confirmed that litigation can extend case timelines and delay processes. Ms. Wright elaborated that she would like to convey to the public that the Board takes these matters very seriously and public protection is priority. She added that Board Members too are frustrated since the system that has a lot of red tape. She concluded that the complaints that the public has are so much bigger than the Board and the individuals that make up the Board.

Ms. Wright stated that sometimes the Members are limited in terms of what they can say to the public, but that does not mean that the Members, and the staff do not care about the issues. The public might not know how hard the Board works to be fair in the panels.

Ms. Hollingsworth commented that she has some concerns and questions about the Board's disciplinary guidelines. All too often these disciplinary guidelines are disregarded and all too often doctors found responsible for patient deaths through gross negligence are being allowed to plead down to public letters of reprimand. She recited past cases and rulings from the Board and noted that the current guidelines are too lenient as opposed to previous guidelines.

Ms. Hollingsworth stated that Board Members are supposed to review guidelines and follow them when deciding on discipline and the bottom line is supposed to be public protection, however more often than not, the discipline does not ensure public safety. Instead, it protects the doctor's practice and reputation.

Dr. Garza inquired about the process that occurs when complaints go through the Central Complaint Unit and there is a closure letter sent out to the complainant. Specifically, she asked why the letter cannot be more detailed instead of just providing the statutes.

Dr. GnanaDev noted that the Board is working on the letters. He added that this is a change that the public might see in the future.

Mr. Andrist expressed that the presentation is not representative of real life. He highlighted the fact that that an accused doctor can challenge the Board with a writ, but victims do not have an avenue of appeal. Mr. Andrist detailed his personal experience with the complaint process, stating that he was never interviewed. In addition, the complaint was closed without a secured copy of his sister's medical records.

Mr. Andrist concluded that his point is that patient safety is not happening enough and that people are being harmed. He cited codes and cases of the Board and commented on how they did not follow the guidelines.

Ms. Monseratt-Ramos mentioned that California consumers and the Board have a conflict with the goal, consumer protection not discipline. She added when a patient dies in a hospital or a medical facility with no cause given for the death or unusual circumstances, consumers expect discipline for a physician. She noted that in her complaint she provided two autopsy reports, but the case was closed since the Board did not find it worthy to investigate. Ms. Monseratt-Ramos added that there is no place else in the state of California where a person can die and it will not be investigated.

Ms. Monseratt-Ramos stated that if the Board continues to promote that the goal is consumer protection, doctors must be investigated. A way in which this can change would be to include consumers in the process. She commented that it is inadequate to file a complaint and have no means to respond before a complaint is closed. Ms. Monseratt-Ramos stated that the Board's main concern is physician rehabilitation versus consumer protection.

# Agenda Item 17 Discussion and Possible Action on Recommendation from the Special Faculty Permit Review Committee

Dr. Bholat noted that the Special Faculty Permit Review Committee held a teleconference meeting on January 2, 2018. The Committee reviewed and discussed Dr. Rickard Braanemark's application for a special faculty permit appointment with the University of California, San Francisco School of Medicine (UCSF).

Dr. Bholat mentioned that Dr. Braanemark specializes in the area of orthopedic osseointegration, specifically in the area of transdermal osseointegration bone-anchored implants.

Dr. Bholat detailed that Dr. Braanemark has held the position of president of the Orthopedic Surgical Osseointegration Society since 2007 and is a member of the International Society for Prosthetics and Orthotics. Dr. Braanemark has been awarded the UCSF Presidential Chair Award, Brian and Joyce Blatchford Award for Amputation Research, and is considered an international expert in orthopedic osseointegration. Dr. Bholat noted that Dr. Braanemark has performed several hundred osseointegration surgeries throughout the world, has articles published in top ranking surgical and engineering journals, and is sought after nationally and internationally for his expertise regarding transdermal osseointegrated bone-anchored implants.

Dr. Bholat explained that if approved by the Board, Dr. Braanemark will hold a full-time faculty appointment as a Professor of Clinical Orthopedic Surgery at UCSF. She added that Dr. Braanemark will provide patient clinical care, teach, and mentor residents and students in the Osseointegration Center at UCSF. In addition, Dr. Braanemark will also continue his research on the Defense Advance Research Programs Agency at UCSF.

Dr. Bholat noted that as of January 8, 2018, Dr. Braanemark has held a facility registration at UCSF for two years and the registration has been renewed until January 8, 2019. Pursuant to B & P Code section 2168.1(a)(5), an individual applying for a special facility permit shall not have held a position under section 2113 for a period of two years or more preceding the date of the application. However, the Board has the discretion to waive this requirement.

Dr. Bholat confirmed that the SFPRC has reviewed Dr. Braanmark's application and qualifications and recommends that the Board grant the wavier and approve Dr. Braanemark for a special faculty permit appointment.

Dr. Lewis made a motion that the Board approve Dr. Braanemark for a Business and Professions Code section 2168.1(a)(1)(B) Special Faculty Permit appointment at UCSF and grant a waiver pursuant to Business and Professions Code section 2168.1(a)(5); s/Dr. Krauss. Motion carried unanimously (9-0).

# Agenda Item 18 Update, Discussion, and Possible Action on Recommendations from the Midwifery Advisory Council Meeting

Dr. GnanaDev thanked Ms. Sparrevohn for her service to the Board as the Chair of the Midwifery Advisory Council (MAC) and as a member since the MAC's inception. He noted that she will no longer be on the MAC after her term expires.

Ms. Sparrevohn pointed out the changes to the licensed midwife annual reporting tool, primarily it will improve the data collection system and ensure that the data collected is reflective of what is happening in the community. She also noted her excitement with the progress of the community college program at American River College in Sacramento. It will educate both midwife assistants and licensed midwives and it is the second of its kind in the nation.

Ms. Sparrevohn requested a motion for the approval of the following agenda items for the next MAC meeting: an update to revisions on the licensed midwife annual report; an update on the Midwifery Task Force, including an update from the Senate B&P Committee staff on an interested parties meeting; an update on regulatory efforts pursuant to Assembly Bill 1308; an update on hospital transfer forms; an update on the midwifery related legislation; selection of new members to the MAC; a discussion and possible adoption of term limits for MAC members; and an update on the new program for midwife mentoring. Ms. Sparrevohn noted that there needs to be approval for an update from the chair, update on the midwifery program, and an update on the community college licensed midwife program.

Dr. Krauss made a motion to approve the agenda items for the MAC meeting; s/Dr. Lewis. Motion carried unanimously (9-0).

Agenda Item 20 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, DCA, provided a description of his background prior to his new job with DCA. He began his update with information regarding the Director's Quarterly Meeting scheduled for January 29, 2018. Those in attendance would be board executive officers, bureau chiefs, and board presidents. The purpose of the quarterly meeting is to ensure that the DCA Director is available to hear issues of the various boards and bureaus. Mr. Le noted that specifically the meeting will cover the DCA strategic plan and actions items.

Mr. Le discussed the DCA future leadership development program, the mentees have been a part of special leadership exercises and are working on special projects to make a positive impact on DCA.

Mr. Le mentioned the executive brown bag meetings. The SOLID team has conducted a series of structured social gatherings to provide a way to transfer knowledge, build trust, and establish network relationships. The next gathering is February 28, 2018, and will include a presentation on employee engagement.

Mr. Le's final update was on required Board Member orientation training. He provided dates for future trainings. He reminded Members they are required to take this training within one year of appointment or re-appointment.

### **Agenda Item 19** Presentation on the Licensing Outreach Program

Ms. Toof presented on the Board's outreach program. She provided some background on the program, including how it came to be, and what it is today. She detailed the functions and purpose of the outreach program, including providing presentations at resident orientations and participating in licensing workshops. She stated that the licensing workshops provide applicants a place where they can complete most of the requirements for submitting an application, and can also ask her questions on the completion of the application and application review. She explained that not only did she reply to questions, but did a preliminary review of the application to ensure that all of the responses were provided and also explained the additional documents the applicant would need to obtain.

Dr. Hawkins asked how many residents per year the program reached.

Ms. Toof commented that she believes it is about 300, but she would confirm.

Dr. Krauss offered that the physician Members of the Board might be helpful in contacting medical schools to provide more opportunities for outreach.

Dr. GnanaDev noted that the Board has received calls that an applicant did not apply in time and therefore could not complete their third year. He added that this is a huge issue.

Dr. Garza inquired about the foreign liaison division that is no longer available. Her second question was why California has a PTAL letter. Her final question was what the intent of a four month training for a resident is and if the Board has considered the impact on other specialties.

Dr. GnanaDev stated staff in the Licensing Program could assist her with responses to her questions.

# Agenda Item 21 Presentation on the Center for Healthcare Quality of the California Department of Public Health (CDPH)

Ms. Crist noted that the focus of her presentation would be an overview of the Center for Health Care Quality, defining what they do, what they do not do, and a discussion of the opportunity of collaboration between CDPH and the Board as it relates to regulatory enforcement.

Ms. Crist detailed that the Centers for Health Care Quality (CHCQ) has two specific areas, one is the Licensing and Certification (L&C) Program and the other is the Healthcare and Associated Infection (HAI) Program. The L&C Program licenses health facilities and certifies them for Medicare and Medi-Cal participation. In addition, it also certifies nurse assistants, home health aides, hemodialysis technicians, as well as nursing home administrators.

Ms. Crist detailed that the HAI Program conducts activities for prevention, surveillance, and public reporting for healthcare associated infection rates. She commented on the workload the L&C Program receives and the field work involved. Ms. Crist spoke about enforcement, which deals with revocations of state licensure, citations with monetary penalties, federal civil monetary penalties, and identifying deficiencies that require facility plan correction.

Ms. Crist noted the items that fall outside of the jurisdiction of CHCQ, such as physician-owned ambulatory surgical centers, urgent care centers that are not listed as primary care clinics, and professionals that are licensed by regulatory boards. Lastly, she noted the potential responsibility for the facility related to physician misconduct and opportunities for collaboration with the Board.

Dr. Krauss thanked Ms. Christ for her presentation and discussed an article that he read in the Los Angeles Times in regard to CDPH. He highlighted the importance of information sharing between agencies. He noted that the public can be better served if there is a transparency between agencies, which could provide a direct link to the consumer.

Dr. Bholat asked for more information on the HAI Program.

Ms. Christ noted that CDPH is trying to figure out what is best for the program, taking into consideration what little resources are available. She noted that this would be an area of opportunity to collaborate with the Board.

## **Agenda Item 22 Update from the Enforcement Committee**

Dr. Yip noted that at the Enforcement Committee meeting Ms. Delp provided an enforcement program update. She provided statistical information regarding the volume of complaints investigated by Board staff, HQIU, and the AG's Office and the timeframe to complete investigations. He noted that even though the number of complaints in fiscal year 2016-17 has increased from the prior fiscal year, most enforcement programs have reduced the time to investigate and adjudicate complaints.

Dr. Yip added that Ms. Delp provided an update regarding enhancements the Board has implemented in the investigations of B&P Code section 805 and 805.01 reports. Educational letters have been sent to 22 entities that are required to submit reports because the report either lacked sufficient information to investigate the complaint, or the report was submitted late. Dr. Yip elaborated that Board staff had prepared 61 subpoenas for records to assist HQIU with the investigation of these reports, which has helped reduce the overall case investigation time frame.

Dr. Yip announced that expert reviewer training is scheduled to take place in Southern California on September 22, 2018. The Board staff is actively trying to secure a location for an expert reviewer training in San Diego and possibly Sacramento in September and October of 2018.

Dr. Yip detailed that he attended the January 8, 2018, enforcement meeting in Sacramento. Those at the meeting included members of the Board's executive staff and program management, as well as representatives from HQIU and HQES. During the meeting several enforcement matters were discussed, including the processing of medical exemptions, unlicensed complaints in the parallel prosecution model, and general case processing issues. Dr. Yip noted that the meeting was beneficial for all parties.

Dr. Yip added that Mr. Hegelein and Mr. Davis gave an informative presentation regarding the vertical enforcement investigative process. The presentation demonstrated all the phases involved with investigating complaints and the efforts of the investigators and the prosecuting attorneys to ensure that complaints are investigated fairly.

Mr. Andrist stated that it does not matter how the Board comes to a decision, it matters whether or not the public has been protected. If the Board's procedures are not accomplishing this, the Board should be working to change the procedures. Mr. Andrist noted that the Board should be asking if actions taken are in an effort to protect the public regardless of what the AG's Office or the administrative law judge recommend.

Mr. Andrist stated the Board ignored the public, the public's pleas, and there is never an attempt to meet to try and make the Board better. He further noted that it is very suspect that there is no patient safety advocate on the Board. Mr. Andrist suspects that the physician Members of the Board fear that they would not be able to control a patient safety advocate as they can other Board Members from the public.

## Agenda Item 23 Vertical Enforcement Program Update from the Health Quality Enforcement Section

Ms. Castro stated that the AG's Office appreciated the opportunity to report with HQIU on the investigatory process at the Enforcement Committee meeting.

Ms. Castro reported that Mary Cain Simon joined the AG's Office in the San Francisco office as a Supervising Deputy Attorney General. She noted that Ms. Simon has a multitude of experience in administrative mandates and profound experience with civil litigation. Her recent hire will uphold the mission of the Board and protect the public.

Ms. Castro mentioned that there are two new lead prosecutors, Machaela Mingardi, who has been working on B&P Code section 805 and 805.1 issues, and Jannsen Tan who has a very high record of suspension orders being issued.

Ms. Castro thanked Lynn Dombrowski for her service as a lead prosecutor in San Jose.

Ms. Castro noted that the AG's Office and HQIU are committed to continuing to work on timelines, improve processes, and engage in a very robust cast disposition review.

### Agenda Item 24 Update from the Attorney General's Office

Ms. Castro noted that the AG's Office complied with B&P Code section 312.2, which required an annual report on representation of all DCA clients. She noted that the information is posted on the website and has been provided to Ms. Kirchmeyer and Ms. Lally.

## Agenda Item 25 Vertical Enforcement Program Update from the Health Quality Investigation Unit

Ms. Nicholls, introduced Mr. Hegelein, who oversees the northern California HQIU field offices located in Sacramento, Concord, San Jose, and Fresno.

Mr. Hegelein reported that seven sworn investigators started with HQIU in January 2018. Six of the seven new hires have received their POST basic certificate, and, therefore, do not require academy attendance. These individuals filled positions in the San Jose, Rancho Cucamonga, Cerritos, San Diego, Valencia, and San Dimas field offices. Mr. Hegelein commented that with this newly hired staff there are now 23 vacancies, which is a 30% vacancy rate. He added that there are 25 candidates in background and 19 limited-term special investigators working in the HQIU to assist with workload.

Mr. Hegelein stated that the Division of Investigation has been granted priority status with CalHR for the psychological and medical portion of the background investigation. This means that candidates are completing the process more expeditiously.

Mr. Hegelein informed that in December HQIU completed a mini training academy for new investigators. Participants provided positive feedback and for this reason, HQIU is planning on hosting similar trainings in Fall 2018.

Mr. Hegelein stated the closed case average for the previous month was 530 days. This includes an average of 18 days for the Board and the AG's Office to complete the disposition of the case. He noted that this is a high number and demonstrates that older cases are being closed. All cases are prioritized by which present the greatest threat to the public. He stated that there are some cases that have received less attention due to the nature of the allegation. Mr. Hegelein commented that as HQIU becomes fully staff, the number will reduce and the goal is to have every case investigated in a year or less. Reduced caseloads will also positively impact the aged case average.

Mr. Hegelein explained that HQIU sworn staff have a high percentage of overprescribing cases. These cases are complex and take longer to investigate. This is due to multiple patients being involved and in some cases, multiple undercover operations are needed. He detailed that as of December 14, 2017, 30% of all sworn cases involved allegations of overprescribing.

Mr. Hegelein commented that HQIU attended an Enforcement meeting on January 8, 2018, with the Enforcement Committee Chair Dr. Yip, Board staff, and AG's Office staff. A new process was approved for the frontline review of overprescribing cases that will consist of the entire CURES report being reviewed by an expert who can assess if there are concerns and identify patients before the case is sent to the field office. He added that this will improve timelines for these cases and HQIU looks forward to the implementation.

Dr. GnanaDev clarified that Mr. Hegelein noted that the timelines would be decreasing.

Mr. Hegelein confirmed that this was stated.

Dr. Bholat inquired when the physicians are looking at the overprescribing cases, is there a report that provides the milligram morphine equivalent dosage (MED). She also questioned if there is information that provides other concomitant prescriptions.

Ms. Nicholls confirmed that this information is taken into consideration by both the medical consultant and the expert reviewer.

Dr. Bholat noted that these reports would be helpful for the Board to see to determine the type of case.

Ms. Castro commented that there is a tool available in CURES 2.0 that measures the MEDs. She confirmed that it is an analytical tool that the AG's Office utilizes during the investigation of the case.

Dr. Yip inquired if the medical consultants are employed by HQIU. Ms. Nicholls confirmed that they are staff of HQIU. Dr. Yip asked how many medical experts there were all together. Ms. Nicholls responded that there are approximately 23 currently, although HQIU is undergoing the process of hiring more for the Fresno office.

Dr. Yip questioned if there is a chief medical officer that oversees the program. He noted that the medical consultants play a vital role.

Ms. Nicholls stated that there are minimum qualifications that are need to be met for all new hires. There is an examination that is taken, scored, and ranked. In addition to this, there are interview panels.

Dr. Yip asked if they are full-time workers.

Ms. Nicholls noted that they are part-time and considered permanent intermittent. She added that most consultants work one to two days a week in a field office.

Ms. Kirchmeyer noted that the 23 medical consultants under HQIU that have been mentioned, work with the investigator. When the case is received they help conduct the interview, answer technical questions for the investigator, and assist in putting together the package for the physician interview. Ms. Kirchmeyer clarified that this group of medical consultants do not approve or deny whether a case goes forward. They have a very limited role. Ms. Kirchmeyer added that the expert reviewers are the people that opine on the case and testify at hearing. Expert reviewers are not employees of the Board, rather they are independent contractors contracted to perform these reviews.

## Agenda Item 26 Items for April Board Meeting in the Los Angeles Area

Dr. Krauss requested a presentation about sobering centers and mental health acute care centers.

Dr. Krauss asked to hear from someone from the AG's Office in reference to Board harassment. He remarked that would like to better understand the Board's obligations and limitations.

Dr. Bholat inquired if more information could be given about the restrictions for stem cell and transplant recipients due to the use of cannabis.

Mr. Andrist requested that the Public Records Act be put on the agenda. He expressed his frustration that it is not the first time he has made this request and that he will continue to request this item until it is added to the agenda.

Ms. Hollingsworth asked if an agenda item could be added to discuss requiring doctors on probation for sexual misconduct to notify their patients.

## Agenda Item 27 Adjournment

Dr. GnanaDev adjourned the meeting at 11:50 a.m.

Dr. GranaDev President

Dr. Lewis, Secretary

Kimberly Kirchmeyer Executive Director

<u>4/19/18</u>

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