

MEDICAL BOARD OF CALIFORNIA QUARTERLY BOARD MEETING



Hilton Sacramento Arden West Folsom Room 2200 Harvard Blvd. Sacramento, CA 95815

Tuesday June 4, 2013

MEETING MINUTES

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

Agenda Item 1 Call to Order/Roll Call

Dr. Levine called the meeting of the Medical Board of California (Board) to order on June 4, 2013 at 10:13 am. A quorum was present and due notice was provided to all interested parties.

Members Present:

Sharon Levine, M.D., President Michael Bishop, M.D. Silvia Diego, M.D., Secretary Dev GnanaDev, M.D Reginald Low, M.D. Denise Pines David Serrano Sewell, J.D. Janet Salomonson, M.D. Phil Tagami Felix Yip, M.D. Barbara Yaroslavsky

Members Absent:

Gerrie Schipske, R.N.P., J.D, Vice President

Staff Present:

Susan Cady, Staff Services Manager, Central Complaint Unit Ramona Carrasco, Central Complaint Unit Manager Dianne Dobbs, Department of Consumer Affairs, Legal Counsel Kathryn Hayes, Licensing Program Manager Rashya Henderson, Investigator Kurt Heppler, Staff Counsel Cassandra Hockenson, Public Information Officer Teri Hunley, Business Services Office Manager Diane Ingram, Information Systems Branch Manager Kimberly Kirchmeyer, Deputy Director Mark Loomis, Investigator

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Armando Melendez, Business Services Analyst Cindi Oseto, Licensing Program Manager Regina Rao, Business Services Analyst Paulette Romero, Central Complaint Unit Manager David Ruswinkle, Associate Governmental Program Analyst, Enforcement Kevin Schunke, Licensing Outreach Manager Jennifer Simoes, Chief of Legislation Laura Sweet, Deputy Chief, Enforcement Renee Threadgill, Chief of Enforcement Lisa Toof, Administrative Assistant II See Vang, Business Services Analyst Kerrie Webb, Legal Counsel Curt Worden, Chief of Licensing

Members of the Audience:

G.V. Ayers, Consultant, Senate Business, Professions, and Economic Development Committee Gloria Castro, Senior Assistant Attorney General, Attorney General's Office Don Chang, Department of Consumer Affairs, Legal Office Yvonne Choong, California Medical Association Zennie Coughlin, Kaiser Permanente Julie D'Angelo Fellmeth, Center for Public Interest Law Hank Dempsey, Chief Consultant, Assembly Business, Professions, and Consumer Protection Committee Bryce Docherty, California Ambulatory Surgery Association Karen Ehrlich, L.M., Midwifery Advisory Council Reichel Everhart, Department of Consumer Affairs Faith Gibson, Licensed Midwife Sarah Huchel, Consultant, Assembly Business, Professions, and Consumer Protection Committee Dorothea Johnson, Department of Consumer Affairs, Legal Office Tina Minasian, Consumers Union Safe Patient Project Jeff Sears, Department of Consumer Affairs, Human Resources Office Taryn Smith, Senate Office of Research Dave Thornton

Agenda Item 2 Introduction and Swearing In of New Board Member; Mr. Phil Tagami

Dr. Levine introduced Mr. Tagami. She announced that he was appointed by the Governor in May of this year and presented his background in both public and private sector. Dr. Levine then welcomed Mr. Tagami as a Board Member and officially swore him in.

Dr. Levine requested that Lisa Toof note for the minutes that Mr. Serrano Sewell had arrived.

Agenda Item 3 Public Comments on Items not on the Agenda

Ms. Yvonne Choong, California Medical Association (CMA) spoke in regards to discussion that took place at the February Joint Forum to Promote Appropriate Prescribing and Dispensing that was co-

sponsored by the Board and the Board of Pharmacy in regards to corresponding responsibility on the part of pharmacists and the need for pharmacists to

verify prescriptions before dispensing medication. CMA, while working with the California Pharmacists Association, has identified some confusion among members regarding the definition of appropriate corresponding responsibility and how it is being exercised.

The CMA found that there are a lack of guidelines and standardization about the appropriate amount of information needed by the pharmacist in order to verify the legitimacy of the prescription. Some of the physicians have received requests for extended portions of the medical records, MRI's, etc. Some pharmacists have wanted to look at the medical records and collaborate with the physicians regarding the diagnosis before dispensing the medication. This has caused some disruption in patient care and in some cases threats of enforcement action against physicians for failure to comply.

CMA and the California Pharmacists Association are requesting a presentation which would include a presentation by the Board of Pharmacy and a discussion on this issue at the next Board Meeting.

Agenda Item 4Approval of Minutes from the April 25-26, 2013 Meeting

A few edits, typographical in nature, were requested by the Members. Dr. Levine asked for a motion to approve the minutes with the edits discussed. Ms. Yaroslavsky made a motion; s/Ms. Diego. Mr. Tagami abstained. Motion Carried.

Agenda Item 5 Closed Session

Dr. Levine announced that the Board Members received an email from the Executive Director, Linda Whitney advising the Board and Ms. Kirchmeyer of her intention to retire effective June 1, 2013, which she did. Dr. Levine stated that the only outstanding matter to be considered in closed session is the appointment of an Acting Executive Director and that once the Board takes an action on this matter, the meeting will return into open session and announce the results of the closed session.

Dr. Levine announced that the Board was now in closed session and asked everyone who was not part of closed session to please leave the room.

The open meeting ended at 10:25 am and went into closed session. Closed session adjourned at 12:10 pm. Dr. Levine announced a Lunch Break and requested that open session reconvene at 12:35 pm.

Dr. Levine reconvened the meeting of the Board in open session at 12:45 pm.

Agenda Item 6 Announcement of Actions Taken in Closed Session

Dr. Levine stated she was pleased to announce that the Members of the Board unanimously voted to ask Kimberly Kirchmeyer to serve as Interim Executive Director as a search process is completed for a permanent replacement for the position. Dr. Levine stated that the Board Members had the opportunity to have a conversation with Ms. Kirchmeyer and the Board expressed their confidence in Ms. Kirchmeyer's ability to lead the Board staff and to work with the Board to set out a vision. Additionally, the Board Members requested Ms. Kirchmeyer help the Board begin to do the important

work that lays ahead in the next months and years to ensure that not only is the Board committed to consumer protection but that the fact of that is known and trusted by members of the public.

Agenda item 7Discussion of Procedures for the Selection of a New Executive Director,
depending on the action of Agenda Item 5

Dr. Levine introduced Mr. Jeffrey Sears from the Department of Consumer Affairs (DCA) and stated that he will discuss the procedures for the selection of a new Executive Director.

Mr. Sears thanked the Board for allowing him the opportunity to be there and stated that the DCA shares the Board's confidence in Ms. Kirchmeyer's abilities. He mentioned that DCA has worked with Ms. Kirchmeyer for many years and looks forward to working with her for many more.

Mr. Sears presented the Board Members with a summary sheet of the typical process that the DCA uses for selecting a new Executive Director.

Mr. Sears stated that the first step in the process is for the Board to appoint a Selection Committee (Committee) which can be done either by appointment or by volunteers. The Committee would then work with the DCA office of Human Resources throughout the process. Components of the selection process are an evaluation of the duty statement for the position and updating revisions, if necessary, determination of the recruitment methodology, and approval of the recruitment bulletin.

Mr. Sears stated that it would also be the responsibility of the Committee to review applications and resumes when they come in and determine which meet the criteria that the Committee establishes for the screening of the initial applications. The Committee can then either interview their top candidates or they can forward those top candidates to the Board for a full Board interview in the future. Typically, the Committee will do an initial interview before forwarding the top candidates to the Board for consideration.

Much of the staff work is done by DCA Human Resources staff, however it is a significant responsibility and workload for the Selection Committee. He suggested to the Members who wish to volunteer, to please think about that workload since the pace that this process moves forward depends on how fast the Selection Committee can take on their components of this process including conducting initial interviews, scheduling screening criteria, and actual screening of the applications. Dr. Levine then asked for Board Member volunteers to sit on the Selection Committee for the recruitment of the new Executive Director.

Dr. GnanaDev and Mr. Tagami both volunteered. Dr. Levine thanked them both as well as Mr. Sears.

Agenda Item 8Status Update on Actions Taken at the April 25-26, 2013 Quarterly Board
Meeting

a. <u>Enforcement Program</u>

Legislative Update: Senate Bill 62 (Price) – Ms. Simoes

Ms. Simoes stated that this is the bill that would require coroners to report deaths to the Board when the contributing factor in the cause of death is related to toxicity from a Schedule II, III, or IV drug. At the last board meeting, the Board voted to change its position on SB 62 from Support if Amended, to Support due to the amendments taken. A support letter went out on May 8th to Senator Price and the Senate Appropriations Committee. This bill was heard in Senate Business, Professions, and Economic Development Committee on April 29, 2013, and she testified in Support of SB 62. This bill was put on the suspense file due to the fiscal impact identified. However, this bill passed out of Senate Appropriations. (7-0) on May 23, 2013, and passed out of the Senate (39-0) on May 28, 2013. This bill is now in the Assembly. The next step will be for it to be heard in the Assembly Business, Professions, and Consumer Protection Committee, however, a hearing date has not yet been set for this bill. Staff will continue to work with the author's office, Assembly Business and Professions Committee and interested parties on this bill.

Dr. Levine asked if there had been any amendments subsequent to the bill since the last Board Meeting. Ms. Simoes stated that there had not been any changes.

Use of CURES Data – Ms. Threadgill and Ms. Cady

Dr. Levine invited Laura Sweet to make the CURES presentation.

Dr. Levine stated that the Medical Board has a large stake in the functionality and accessibility of the CURES program, California's prescription drug monitoring program. It is currently in a situation where its funding will expire June 30, 2013. Ms. Sweet stated that she believes there is pending legislation that will address this issue.

Dr. Levine stated that is a critical piece of the Board's work and also a critical piece of the work flow of prescribers and dispensers in the State.

Ms. Sweet gave a report on CURES, starting with a brief background about CURES and how the investigation utilizes the CURES. CURES stands for Controlled Substance Utilization Review and Evaluation System and is currently administered by the Department of Justice (DOJ). It originated from the triplicate prescription program that was created in 1940. Currently CURES collects schedules II, III and IV prescription information on a weekly basis via an electronic data system and allows preregistered practioners, pharmacists, and law enforcement officers access to it on an instantaneous basis 24 hours a day. She discussed the CURES Patient Activity Report, the information it identifies, and the benefits of this report to the prescribers and the patients. Ms. Sweet's report also included the steps the field investigators use for investigations. She included several examples of Prescriber Prescription History and what the history reports include. She stated that the CURES report cannot be relied upon on its own basis for demonstrating the State's burden of "good cause". The Investigator must procure all of the individual prescriptions to ensure the CURES report is accurate to be certain the Board has the accurate evidence, which is a very time consuming process.

Ms. Yaroslavsky asked if as part of the refinement of the CURES program, would it be helpful for the Board staff to have some kind of methodology to pull out of CURES certain identifying criteria for a patient as well as for physicians.

Ms. Sweet responded that it would be helpful but it is not an option at this time, but with the proper funding, data extracting could definitely be an option.

Dr. GnanaDev asked, if a patient comes to him, what kind of information can he obtain from CURES.

Ms. Sweet responded saying if a physician is signed up for the Patient Activity Report, he can query that patient, request that patient's activity report and it would let him know who is prescribing to this patient, what they are receiving of the scheduled medications and where those medications are being prescribed.

Ms. Sweet stated that it is a very useful tool for prescribing physicians, but it is not as accurate as staff would like it to be.

Dr. GnanaDev stated that he has had some emergency room doctors come to him and complain stating that they cannot sign up for CURES database.

Ms. Sweet responded that issue is due to a lack of funding for the program.

Ms. Yaroslavsky asked if there should be a law in place that says that any physician that is allowed to prescribe schedule II, III or IV drugs has to be a participant in the CURES program.

Dr. Levine responded saying that once CURES is updated, that would be the time to look at requirements about the mandatory use of CURES and that currently 12 percent of physicians and about 8 percent of pharmacists in the state are signed up for CURES.

Ms. Sweet finished her presentation by discussing the pain management guidelines, the subject interview, and the expert reviewer decision options.

Dr. Levine asked if the DOJ has a way to monitor the extent to which pharmacies are submitting, on a weekly basis, the reports they are supposed to be submitting.

Ms. Sweet responded that she is not able to answer that question, but would find out and get back to her.

Mr. Tagami stated that he appreciates the data coming in and would like to know if Ms. Sweet has a recommendation for the Board, looking at specifically what direction the Board should take.

Ms. Sweet responded that staff believes a task force or staffing similar to what the Board has for the Operation Safe Medicine unit, which is a unit dedicated to unlicensed activity, would be the best approach since these are time consuming cases. This would extract these cases from current investigator caseloads, which would improve time frames.

Mr. Tagami responded stating that the next question is how to differentiate from what the professionals who do this every day are requesting by way of tools and suggestions. Those recommendations would need to be accompanied with costs, at what other permission and/or communications are required to make it effective and how much time is needed to implement it. Ultimately it is looking to perfect a case that a judge will then support, that can be acted upon to bring closure and enforcement. That is a piece of this that needs to come into focus and that from that specifically what the "ask" of the Board is by way of permissions as it relates to funding and process to make sure that a new program is implemented. In addition, the Board needs to know if the funding sources are readily available or able to be re-directed, what the implementation time is, and what the checkup is to make sure this new direction and program has the impact that was intended.

Dr. Diego asked how a physician would know he/she was deviating from the Pain Management Guidelines, and does the Board post that information on the Web site.

Ms. Sweet stated that and article regarding the guidelines has been in the Newsletter at least three times and they are posted on the Web site.

Dr. Levine stated that there are two sets of guidelines, one is the pain management guidelines and the second is the appropriate prescribing guidelines for opioids. At the last Enforcement Committee meeting the Committee had asked that a task force be convened to include interested parties to look at possible needed revisions to these guidelines. Dr. Bishop and Ms. Yaroslavsky had agreed to co-chair that task force. CMA had also offered resources. There are a lot of changes in opioid prescribing and this is a perfect time to actually relook at it.

Ms. Yaroslavsky suggested that staff give a timeframe that they will bring back to the Task Force members when this is going to roll out.

Dr. Low suggested the Board create within enforcement a unit dedicated to addressing the problem of overprescribing and CURES review would be a part of that unit. The Board should have the resources since it is dedicating a certain number of investigators towards those efforts anyway, so there is no reason not to create a focused unit within enforcement looking at overprescribing and addressing those problems.

Dr. Levine asked Ms. Sweet if that was feasible.

Ms. Sweet responded that at the current time, she does not believe it is feasible as the Board does not have enough staff at this point in time.

Dr. Levine asked Ms. Sweet to work with staff to see what it would take to create a dedicated unit in terms of resources, training, expense, etc. within the investigative unit in enforcement to actually address the problem. A revamped CURES where the Board could have confidence in the data would be part of that with hopes that will be in process soon.

Ms. Sweet stated that DOJ manages the CURES database and that staff has no access to make program changes, etc.

Dr. Levine recommended collaboration with DOJ to achieve this goal.

Dr. GnanaDev stated he felt this is an important issue, not just on the enforcement side, but on the prevention side and made a motion that staff present at the next board meeting what it will take to create a special investigative unit on the prescription drug overdose and how staff can work with other agencies on the CURES database availability, signing up, etc.

Mr. Tagami requested expanding the request to include a work plan, a budget, a schedule, a list of other stakeholders that need to be engaged by way of what recommendations and steps they see or need and also taking a look at suggestions and recommendations from other states by way of best practices and find out if there have been any similar programmatic changes or reforms done to address these specific issues. Then as that becomes concurrent and the program is going forward, then have staff come back to the Board with a status update and discuss how to go about inviting stakeholders in to communicate with the Board.

Mr. Heppler stated that this type of request made to the staff by the Board can take place without a motion since the Members are directly guiding the Board's own staff to present a comprehensive report and to have it ready for consideration by the Board at the next available opportunity.

Mr. Tagami then requested that this be agendized for action at a future meeting so that the Board can then affirm and adopt steps that would be concrete associated with action and time.

Dr. Low stated that the Board has to be very realistic in what it alone can do quickly and effectively and what its obligation are to the public. He believes that the Board should not be bogged down by trying to get everybody else involved and thinks the Board should look specifically at what the Board's roll is in terms of trying to deal with this particular problem of overprescribing. He feels that if this plan becomes too encompassing, it will be difficult to get something done quickly.

Ms. Yaroslavsky suggested that the opportunity for the task force to meet prior to the next Board Meeting with staff's involvement and engagement would be a good vehicle to start this conversation moving forward. She recommended there be an interim meeting either before or after the July meeting.

<u>Cost/Ramifications of Senate Bill 304 (Price) – Proposal to Transfer all Investigative Staff</u> from the Medical Board to Department of Justice – Ms. Kirchmeyer and Ms. Threadgill

Ms. Kirchmeyer began her report with a detailed explanation of the costs of SB 304.

The Board is projecting the costs of this transfer to be approximately \$1.3 million dollars. These costs are related to the reclassification of the investigators into DOJ classifications. These costs only include salaries, not benefits.

The first fund condition in the materials included future costs for the CURES system as proposed in a current budget bill, the Board approved increase in expert reviewer pay, anticipated BreEZe costs, a proposal for a Northern Operation Safe Medicine unit, and other additional enforcement staff. The

proposed future costs have not been approved, but are going through the review process. It is important to know this impact is based upon projected figures.

The second shows the same fund condition with a projected \$2 million dollar reversion this year, which could occur due to vacant positions and other savings the Board is projecting. At the July Board Meeting staff will have a more accurate picture of the actual reversion.

Ms. Kirchmeyer stated staff has discussed this transition with the DOJ and believes they have identified which positions would be transferred to the DOJ, which ones would stay with the Board, and which ones are uncertain at this time.

Ms. Kirchmeyer proceeded through each ramifications. She stated that the following are items that staff believes are ramifications that will occur:

- The funding for the investigator positions would be removed from the Board's salary and wages and moved to the Attorney General line item on the Board's budget as an operating expense.
- The operating expenses in the Board's budget associated with the current investigator positions would be reduced for all overhead costs, including equipment, vehicle maintenance, rent, travel, training, etc., and would be moved to the Attorney General line item in the Board's budget.
- The Attorney General would determine billing methodology and bill the Board an hourly rate for the investigative services currently the Board charges is reimbursed \$149/hour for investigative services for physician and surgeon cases.
- The Investigative staff in the Operation of Safe Medicine (OSM) will not be transferred to the DOJ due to the fact that they do criminal investigations. All other staff in the enforcement unit would remain at the Board (Central Complaint Unit, Discipline Coordination Unit, Probation Unit, Non-Sworn Special Investigative Unit, Central File Unit).
- The Board would need to have an individual designated to review investigation reports to ensure appropriate action was taken, i.e. closure of case or filing of administrative action. More discussion is necessary as to what this individual would do and their review authority.
- The Investigators would be provided increased authority in Penal Code section 830.1, which will allow them to work more efficiently on their cases, specifically prescribing practices and sexual misconduct cases.

Ms. Kirchmeyer stated there are some uncertain ramifications. These include:

- The disbursement of the Office of Standards and Training Unit as staff would be needed at the DOJ; however, a few of the staff may also need to remain at the Board in order to assist with hiring and training the OSM staff and the non-sworn Special Investigators.
- Whether the boards who utilize the Medical Board's Investigators to perform investigations (i.e. Board of Podiatric Medicine, Osteopathic Medical Board of California, Physician Assistant Board, and Board of Psychology) would continue to use the transferred investigators or would use the DCA's Division of Investigation (DOI). Note: Board of Podiatric Medicine utilizes the vertical enforcement model.

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- What would occur when the Board hits the financial threshold for the hours that could be paid to the Attorney General's office from that line item. Would the Board have to halt investigations until July 1 of the next fiscal year? (This sometimes happens with boards who have investigations performed by the Board or DOI.)
- What other positions the DOJ may determine are required to implement this new responsibility and the cost of those new positions.

Ms. Kirchmeyer stated that this could not logistically happen by January 1, 2014 as that is only three months after the bill is signed and all of these items would need to be discussed with the DOJ and the other healing arts boards.

Board staff also gathered information from other states and from the Federation of State Medical Boards. Of the 12 State Boards that responded, nine use their own in-house investigators. Staff provided the Board with the information from the FSMB indicating which boards have authority over disciplinary investigations.

Lastly, staff provided the Board with a copy of the pros and cons that were identified at the last meeting. Staff has not identified any other pros or cons to add to this list, but have provided these ramifications for the Board in order to take a position on this portion of SB 304.

Dr. Low feels that the investigators are like policeman and detectives, and the Attorney General's Office (AG) is like the District Attorney's Office. They are separate and for a good reason. If the Board moves the investigators into the AG's Office, he is concerned that the cases will not get the same degree of scrutiny that the Board gets when they are separate. The concept of investigating complaints is better done by the Medical Board. Other than making things happen more efficiently, he does not see much benefit since the main goal is still public protection and what is best for the public. He questions if it is best to move it under one entity.

Mr. Serrano Sewell agreed with Dr. Low and believes that if this should work out, there needs to be a very clear Memorandum of Understanding (MOU) between the two agencies that memorializes what is in law, etc. The large public policy question is the loss of public oversight. The Board has jurisdiction over its investigators and through that establishes priorities. Should this very important function be turned over to another independently elected office, the oversight from this Board will end. The AG's office will have to be brought into the discussion and that office would have to decide independently how they want to interact with the public.

Ms. Yaroslavsky expressed her concerns about how the Board is are going to hold accountable another public entity. She added that if the Board could hold another public entity accountable, why can the Board not fix the timelines today.

Dr. GnanaDev feels that putting them in a separate entity that is independently elected without the Board having much control does not make sense to him.

Dr. Bishop believes that the drastic action being taken is due to the unresponsiveness of the Board to the concerns of the Legislature. The Board has to show a will to make some changes to do what is right to protect the public. He agrees with the Legislature that the Board has not done a good job at

protecting the public. He thinks that if the Board can come up with a way to demonstrate to the public and the Legislature that it can improve, the investigators should be kept with the Board, and if not, the Board will be forced to have the investigators transferred.

Mr. Tagami stated that from listening to the Members and Staff speak about this issue, that the Board has been wrestling with this issue for some time and believes that this issue should be approached with a beginner's mind. The possibilities are eminent and only the expert sees the limitations. He is seeing that the Board has a good closure rate on complaints and cases. The question before the Board is how are the different parts of the Government going to evolve to deal with new circumstances and behaviors that are coming from the public and in some cases out of practicing physicians. He feels finding the best practices is important and needs to be understood. Working as a team internally is an important part of the solution. He stated that he would be a supporter of keeping the investigative unit with the Board for several reasons. He thinks there are unintended consequences with the division. The steps to address these new concerns that have been evolving and coming to light by the Legislature, the public and the media are all things that can be addressed in a very constructive, responsible way by the Board. He feels that the steps to address the issues have been initiated and believes this is the time to come together and collaborate. He believes there has to be two tracks. There has to be an immediate set of actions demonstrating the seriousness to get this moving, but at the same time the Board needs to look for that outreach, work with the Legislative staff, communicate with the Legislature, the Governor's Office and with the public to address concerns. Mend fences if they need to be mended and move forward in a lasting and sustainable way.

Public comment was heard on this agenda item:

Dave Thornton, prior Medical Board Executive Director, gave a brief background on himself and where he is coming from on this issue. He started doing investigations for the Board in 1975. In 2000, he was promoted to the Board's Chief of Enforcement and held that position for about 3.5 years. In 2004 he was appointed as Executive Director and retired from that position in 2007. The issue of transferring investigators dates back to 2005 with SB 231 (Figueroa). That was the Board's sunset bill. The Board had unanimously voted to approve the transfer of the investigative staff back then. At the last minute, the transfer was pulled out of the bill, but what was not pulled out was the transfer of authority for the investigations where the Board no longer had authority. That authority had been transferred to DOJ. When that transfer of authority happened, DOJ had no investigators at that time. The Board has always had a retention problem and transferring the investigators to DOJ would solve the problem of retention with the investigative staff at DOJ as the salary differential is considerable. He believes the Board would not lose control of the investigative staff as the Board will still control which cases go over to the DOJ, still have control of cases where an accusation is filed, and still have control as a Board over decisions that come to the Board such as stipulated and proposed decisions.

Dr. GnanaDev suggested that the Board should pay its investigators the same salary as the DOJ pays its.

Mr. Thornton reminded the Board that the request has to go through the Department of Personnel Administration (DPA) and they have always been reluctant to upgrade one set of investigator's salary. DPA feels if it gives the salary adjustment to one set of investigators, it would have to give it to all.

Ms. Yaroslavsky questioned why the DOJ can pay their investigators more than other State agencies. Mr. Thornton stated that the DOJ has a "Special Agent" classification that most other agencies do not have, and the salary level had been set for those in that classification.

Dr. Low believes that the Board should do whatever is necessary to be able to adjust the salaries for its Investigators rather than move them to DOJ.

Mr. Tagami asked if staff has statistics on turnover rate of investigators.

Ms. Threadgill stated that staff has done multiple studies with retention having been the focus over many years and can get those statistics for him.

Ms. Threadgill stated that over the last 8 years, their unit had 20 transfers and 20 retirements which is almost half of the entire unit.

Mr. Tagami requested a report on the average tenure of the Board's investigators and how it aligns with other law enforcement. He stated this information would be relevant for decision making.

Public Comment was heard for this agenda item:

Julie D'Angelo Fellmeth, Administrative Director for the Center of Public Interest Law and former Medical Board Enforcement Monitor from 2003 – 2005, stated that CPIL strongly supports the revision in SB 304 to transfer the Board's Investigators to the AG's Office, specifically into its Health Quality Enforcement (HQE) section which has specialized in cases against physicians for over 20 years. She provided several letters of support from Board Members in 2004.

<u>Senate Bill 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) – Proposed Regulation to</u> <u>Incorporate Uniform Standards for Substance Abusing Licensees – Process and Timeline –</u> <u>Mr. Heppler</u>

Mr. Heppler stated that at the last Board Meeting the Board had asked staff to commence the rulemaking process to implement the SB 1441 Uniform Standards. He reported that he and Ms. Dobbs have had some preliminary discussions about how best to accomplish that. He stated that staff will bring language to the July Board Meeting for the Board's consideration. If it meets the Board's approval, the Board could then set the matter for public hearing. That hearing could take place at the October Board Meeting, at which time the Board would consider public and written comment taken during the open comment period. If the language meets the Board's satisfaction, then the Board could close the comment period and prepare the Statement of Reasons without any adverse comment. The Board would then transmit the final regulatory package to the required various control agencies, including the Office of Administrative Law (OAL) for ultimate approval of the regulation.

b. <u>Consumer Protection Enforcement Initiative (CPEI) Positions: Position Description and</u> <u>Plan to fill Non-Sworn Investigator Positions and Timeline – Ms. Kirchmeyer and Ms.</u> <u>Threadgill</u>

Ms. Kirchmeyer gave a very brief background on the CPEI positions. She stated that at the Executive Committee Meeting on January 31, 2013, a presentation was made on the CPEI positions. She stated the Board has the handout in their current packet that was provided at that meeting.

This document described the history of these positions, explained why these positions had not been filled, and explained that these positions were eliminated due to the 5% salary savings drill or Budget Letter 12-03. The Board was notified it could reestablish these positions in its blanket and at the January Meeting staff provided a proposal for reclassifying these positions. However, after that meeting, staff was notified that those positions could no longer be reclassified.

Upon this information staff went back and revived and reviewed the Board's original plan when the positions were established in July and October of 2010 and developed a plan to establish a unit for these positions.

Ms. Kirchmeyer briefly described that these positions are not in the Governor's budget. Looking at the Salaries and Wages section of the Governor's budget for FY 2013/2014, it shows the Board has 281.4 Medical Board positions. 10.3 of those are temporary positions leaving the Board with 271.1 full time permanent positions. This number does not include the CPEI positions because, again, these positions were eliminated, which is why these positions are not counted in the Board's vacancy rate.

The Board can fill these positions as long as it ensures that it maintains an overall salary savings of approximately \$941,000 each year. This amount equates to about a 5% vacancy rate.

As long as the Board maintains these vacancies and this amount, it can fill these positions. The Board needs to remain very cognizant of this and ensure it does not expend its budget.

Ms. Kirchmeyer asked Ms. Threadgill to continue with report.

Ms. Threadgill reported that Board staff has proposed to establish a Complaint Investigation Unit staffed with six (6) non-sworn Special Investigator positions and one Supervising Special Investigator I position within the Enforcement Program. The Board staff has identified a number of case types that can be investigated and referred for prosecution without the use of a sworn investigator. Staff is proposing to redirect the following cases types to non-sworn personnel to investigate:

- Physicians who have been charged with or convicted of a criminal offense or reported an arrest on their renewal application;
- Quality of care investigations following a medical malpractice settlement or judgment;
- Violations of a term or condition required of a physician on probation following a disciplinary action;
- Reports of disciplinary actions taken by another jurisdiction or state;

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- Physicians petitioning the Board for reinstatement of a license following revocation or surrender;
- Physicians petitioning for modification or early termination of probation; and
- Outpatient settings complaints based upon information from the accreditation agencies.

Not all enforcement activities or investigative duties require the use of sworn investigators. Many tasks associated with investigations can be performed by non-sworn investigators such as detecting and verifying violations, interviewing witnesses, gathering information, analyzing testimony, serving legal papers, or serving as an expert witness, among other non-sworn duties. Having non-sworn investigators allows sworn investigators to perform investigative tasks requiring peace officer status such as making arrests or search and seizure, etc. A simple change such as this will help shorten the timeframes on core investigators. A reduced caseload will allow the investigators to complete their investigation in a more timely manner, which is consistent with the Board's strategic goals, objectives, and mission.

Ms. Kirchmeyer briefly went over the time frame showing that on June 3, 2013, staff submitted packages for these positions to the DCA and since these are new positions they have to go through the complete approval process to the DCA Human Resources Office as well as DPA for approval. That is a lengthy process to get through, but once approval is complete, staff will start advertising for those positions and filling those positions at that time.

Public Comment was heard on this agenda item:

Ms. Tina Minasian, on her own behalf stated she does not agree with the way the non-sworn and sworn investigators duties and salaries are set. She would like this issue to be agendized for discussion at a future Board Meeting.

c. <u>Senate Bill 100 (Price) Chapter 645, Statutes of 2011: Task Force on Outpatient Surgery</u> <u>Settings – Dr. GnanaDev.</u>

Dr. GnanaDev announced that the Task Force had not met yet, but will be meeting before the next Board Meeting in July. The Task Force will be looking at the Outpatient Surgery Settings standards to see if they need to be amended and if the task force will need to establish new laws or regulations, etc.

<u>Web site – Mr. Worden</u>

Mr. Worden reported that the accreditation agencies have been providing additional information regarding the outpatient surgery settings that are accredited pursuant to Health and Safety Code Section 1248 and 1248.1 and staff has been updating that information on the Board's Web site. Mr. Worden stated that the Board Meeting packet contained a printout of the Board's outpatient surgery setting webpage that staff have been working on to provide additional information to consumers. The specific additions include the following links:

- Outpatient Surgery Setting FAQs
- Outpatient Setting Complaint Overview/Process

- o Consumer Complaint Form
- Consumer Complaint Form (Spanish)
- o Types of Settings Not Required on List
- o <u>CMS Acronyms</u>
- o <u>CMS Glossary</u>
- o CMS Approved Accreditation Organization Contact Information
- o <u>CMS Accrediting Organization Complaint Contacts</u>

In addition, the Board has requested the accreditation agencies to provide information regarding outpatient surgery settings that have been certified as meeting CMS requirements even though these type of settings are exempt in statute from being accredited and reported. These settings in the near future will be identified by a box on the Web site as CMS.

This information is being provided as a courtesy to California consumers to help them determine if an outpatient surgery setting may be CMS certified. CMS certified settings are exempt from providing any information to the Board and therefore, these listings on the Board's Web site will not have all of the information that is required for an outpatient surgery setting that requires accreditation pursuant to Health & Safety Code sections 1248 - 1248.2.

Staff is also working on providing the inspection reports on each accredited setting's listing in the next few months.

Ms. Serrano Sewell asked if the renewal of the accreditation agencies had been completed, and if not, when the Board expected those applications to be submitted.

Mr. Worden responded that the accreditation agencies had already submitted all of the renewal forms and documentation, however staff has not reviewed them yet.

Mr. Serrano Sewell stated that it appeared from the last meeting that there are differences in the standards across the accreditation agencies. He stated that one agency said it would only accredit outpatient surgery settings in which the physician performing that procedure had the same authority to perform that surgery at an acute care hospital and was certified in that area of practice, but not all accrediting agencies had this as a requirement. Mr. Serrano Sewell stated that maybe the Board should suspend the renewal process, or allow an interim approval for the existing applicants, with the understanding that the Board would exercise its rulemaking authority and promulgate new standards based upon what the Board expects of the accrediting agencies. For example, new standards could be to set a number of unannounced visits/inspections, etc. He stated the Board should take this opportunity and give some serious thought to promulgating new laws or regulations at this time.

Mr. Worden stated that the Outpatient Surgery Setting Task force made up of Dr. Gnanadev and Dr. Salmonson will be looking at the standards to identify any that need to be brought to the Board for possible regulations or statute changes. Mr. Worden added that after the changes go through the regulatory process that would be something the accrediting agencies would have to abide by once the regulations become effective.

Mr. Serrano Sewell asked if there was a way to ensure the accreditation agencies complied with any new requirements before going through the renewal process. Otherwise it will be three years before the entity would have to comply with the new regulations. Mr. Serrano Sewell requested that Mr. Heppler respond from a legal perspective.

Mr. Heppler stated that it seemed the Board wanted to suspend the renewal process, or defer it, with the understanding that there may be some upcoming regulatory developments that would put the subsequent renewal on a higher standard. He stated this is difficult because the renewal and licensing realm is a right. The Board can continue to renew the accreditation agency, and if it falls short of what the standard is then the Board can take administrative disciplinary action and stop that renewal cycle by taking the approval away. So it is not impossible, but it is unusual.

From a public policy perspective, by deferring the renewal, the accreditation agency may be deficient in some regard that the Board will not find because it deferred the renewal for 12 months. He recommended the Board consider that the standards in H&S Code section 1248.15, are minimum standards. The Board may want to consider changing those standards and doing it in an expedited manner.

After discussion, the members decided to continue the accreditation agencies' renewal process and move forward through the Outpatient Surgery Setting Task Force to develop any necessary new laws or regulations.

Complaint Process – Ms. Threadgill and Ms. Cady

Ms. Threadgill explained that the concerns about procedures being performed under anesthesia in an outpatient surgery setting is not a new complaint issue for the Board. Staff has been reviewing complaints regarding outpatient surgery settings for at least 13 years, since Business and Professions Code (B&P) section 2216 was added to the Medical Practice Act.

When evaluating complaints about procedures performed in outpatient surgery settings, staff much first determine whether the setting is one that would fall under the Board's purview and would require accreditation. If the setting is certified to participate in MediCare or is a federally operated facility or a facility operating on a tribal reservation, the setting would be exempt from the requirement to be accredited. If not the Enforcement Program staff would confer with Licensing staff to identify whether the facility is accredited through one of the four approved accreditation agencies.

The next issue that must be considered is identifying whether the procedure was performed with a level of anesthesia that had the probability of placing a patient at risk. It can be difficult to determine if the combination of drugs administered to a patient meets this criteria without input from a medical expert. If the combination of drugs being used does not meet the level of "general" anesthesia, the outpatient surgery setting does not require accreditation.

Ms. Threadgill reported that it is common for issues related to an outpatient surgery setting to be identified through a complaint filed about the quality of care a physician provided. Once the patient's medical records are obtained, staff confirms whether the level of anesthesia was such that would have required the setting be accredited and then verifies if the setting is licensed, exempt, or accredited. If

the setting is not accredited, the complaint is then referred for further investigation, regardless of whether the care and treatment were appropriate.

Ms. Cady referred the Board Members to a chart in their packet that outlined the Board's responsibility in responding to complaints received about the outpatient surgery settings. The Health and Safety Code requires that the accrediting agency perform either an inspection or investigation in response to a complaint forwarded by the Board and provides timeframes for responding back to the Board when the investigation or inspection is complete.

Ms. Cady then referred to another chart that outlined how the Board responds to complaints received specifically naming the outpatient surgery setting. The first step in the process is to determine whether the setting is accredited or not. If the setting is accredited, the complaint will be referred to the accrediting agency for inspection. When the inspection report is received in Licensing, the findings are reviewed to identify if any deficiencies were noted in areas related to patient safety. If so, the inspection report is referred to the Complaint Unit for a formal investigation.

If the setting is not accredited, the complaint is initiated and initially reviewed by the Complaint unit. If the allegations indicate that procedures are being performed under general anesthesia, the complaint will be referred for investigation. A case would also be initiated on the physician who is alleged to have performed the procedure in a setting without accreditation as it could represent a violation of B&P Code section 2216.

Dr. Levine asked about the status and outcome of the California Department of Public Health (CDPH) letter that Ms. Whitney had sent to them back in December 2012 that CDPH responded to in April, 2013. She asked if there has been an MOU signed.

Ms. Kirchmeyer responded by saying there has not been an MOU signed and that staff is in the process of setting up a meeting in the near future with CDPH to get this issue resolved and will have an update for the Board at the July meeting.

Dr. Bishop stated that the Board has to be concerned, not just about whether the outpatient surgery setting is accredited or not, but that an actual trained anesthesiologist is performing these surgeries, as each individual surgery, person, and situation varies.

Public Comment was heard on this agenda item:

Tina Minasian speaking on behalf of Consumers Union, stated her concerns regarding physicianowned outpatient surgery settings and urged the Board to apply rigorous oversight to outpatient surgery settings and their accrediting agencies.

Accreditation Standards – Mr. Worden and Mr. Heppler

Mr. Heppler stated that this agenda item was covered in the prior discussion, and asked the Board if it would like to go over it in more detail or wait until the next Board Meeting where staff would have more information to share since the Task Force will have met by then.

Dr. Levine suggested that the Board wait until the July Board Meeting for further details and also reminded staff that the Board had requested a side-by-side chart of the different standards used by the accrediting agencies.

d. <u>Disciplinary Guidelines (Informational Item) – Dr. Levine</u>

Dr. Levine stated there were two issues that arose through the Sunset Review. One is interim suspension orders (ISO) and the other is disciplinary guidelines. The disciplinary guidelines are intended to create the ability for the Board and the Administrative Law Judges (ALJ) to evaluate the facts and circumstances of a case and to make judgments about the appropriate discipline. Dr. Levine believes the Board is hampered by the current mechanism and format of reporting on discipline and the way it is tracked. It is not capturing, in an extractable way, the rational for deviation. There needs to be a process for capturing that information that can be documented over time and the basis for deviation from the guidelines.

In regards to the ISOs, questions were raised about the number of times it is sought out and why, in some situations, the Board is not successful at getting an ISO. There is pending legislation in SB 304, which contains an extension of the time between an ISO being granted and the time to file an accusation. One of the reasons there is hesitation on the part of the AG's Office is the uncertainty that an accusation can be filed within the 15 day timeframe that is the current statute.

Dr. Levine reported that the Board has approved training for the ALJs on the topic of ISOs to be put on by the Office of Administrative Hearings (OAH). That training is scheduled to take place on June 28, 2013. This training will re-familiarize them with the process, the circumstances, and why the Board will be asking for ISOs.

There will also be a training this summer for ALJs on the Board's disciplinary guidelines through the OAH. The ALJs, in the process of making decisions, need to explain the rationale for either using the guidelines or deviating from them and clearly documenting the reason for the deviation.

Dr. Low requested that the AG's Office adapt a more standardized form in its letters to the Members of Panels A and B. He recommended it use the same format for all offices so that the Members receive the same kinds of information, background, etc. It should state whether or not it is consistent with the disciplinary guidelines and if not, why. In addition, for the stipulations, he would like Board staff to put a note to the Panel Members about the deviation so that it is easy to locate when reviewing cases.

Agenda Item 9 Agenda Items for July 18-19, 2013 Meeting in the Sacramento Area

Dr. Low requested that the Board discuss taking a position on Utilization Review complaints.

Dr. Bishop requested having the California Department of Health Care Services give a presentation to the Board on ways to assist new physicians, coming out of residency, avoid being involved in fraud schemes.

Mr. Tagami would like to have the Board's legal staff clarify what is listed on the agenda that can be an action item. He would also like to see the enforcement issues that were discussed in detail today be agendized for the next meeting for possible action.

Ms. Webb responded to Mr. Tagami's comment on clarifying the agenda by stating that items where action is intended should be identified as an action item clearly on the agenda as opposed to being shown as an update.

Dr. Levine would also like the carry over items from the April Meeting be agendized for the next meeting, including a staff report on follow up to the Joint Forum, an update on the Board of Pharmacy activities, a report on teleconference options, and a report on the gag clause.

Agenda Item 10Adjournment

Dr. Levine adjourned the meeting at 3:50 pm.

Sharon Levine, M.D., President

Silvia Diego, M.D., Secretary

Kimberly Kirchmeyer, Interim Executive Director

The full meeting can be viewed at <u>www.mbc.ca.gov/Board/meetings/Index.html</u>

Date

Date

Date