BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY - Department of Consumer Affairs EDMUND G. BROWN, JR Governor

# **MEDICAL BOARD OF CALIFORNIA**

Agenda Item 3





Embassy Suites 250 Gateway Boulevard South San Francisco, CA 94080 July 27, 2017

## **MEETING MINUTES**

#### **Members Present:**

Felix C. Yip, M.D., Chair Michelle Anne Bholat, M.D. Judge Katherine Feinstein, (ret.) Sharon Levine, M.D. Ronald H. Lewis, M.D. Jamie Wright, J.D.

### **Other Board Members Present:**

Dev GnanaDev, M.D. Randy W. Hawkins, M.D. Howard R. Krauss, M.D. Kristina D. Lawson, J.D. Denise Pines

### **Members Absent:**

Brenda Sutton-Wills, J.D.

### **Staff Present:**

April Alameda, Staff Services Manager II Christina Delp, Chief of Enforcement Rashya Henderson, Supervising Special Investigator I Kimberly Kirchmeyer, Executive Director Regina Rao, Associate Government Program Analyst Elizabeth Rojas, Staff Services Analyst Jennifer Saucedo, Staff Services Analyst Jennifer Simoes, Chief of Legislation Lisa Toof, Administrative Assistant II Kerrie Webb, Staff Counsel

#### Members of the Audience:

Gloria Castro, Senior Assistant Attorney General, Department of Justice David Chriss, Chief of Enforcement, Division of Investigation, Department of Consumer Affairs Zennie Coughlin, Kaiser Permanente Julie D'Angelo Fellmeth, Center for Public Interest Law Louis Galiano, Videographer, Department of Consumer Affairs Marian Hollingsworth, Consumers Union

Agenda Item 3

Christine Lally, Deputy Director, Department of Consumer Affairs

Craig Leader, Senior Investigator, Health Quality Investigation Unit, Department of Consumer Affairs Kathleen Nicholls, Deputy Chief, Health Quality Investigation Unit, Department of Consumer Affairs Michelle Monseratt-Ramos, Consumers Union Safe Patient Project

Mark Scarlett, Supervising Investigator I, Health Quality Investigation Unit, Department of Consumer Affairs

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

Dr. Yip, Chair, called the Enforcement Committee (Committee) of the Medical Board of California (Board) meeting to order at 1:12 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

No public comments were provided.

### Agenda Item 3Approval of Minutes from January 26, 2017 Meeting

Dr. Lewis made a motion to approve the January 26, 2017 meeting minutes; s/Ms. Wright. Motion carried unanimously (6-0).

### Agenda Item 4 Enforcement Program Update

Ms. Delp stated that on July 5, 2017, enforcement staff held a meeting to discuss case processing timeframes, improvements that had been implemented to decrease timeframes, and what additional measures could be taken to efficiently process the work being done by the Board, the Department of Consumer Affairs (DCA), the Health Quality Investigation Unit (HQIU), the Attorney General's (AG's) Office, and the Health Quality Enforcement (HQE) Section. She noted the participants in this meeting from the Board were herself, Dr. Yip, Ms. Kirchmeyer, Ms. Houston, and Ms. Romero. Also present was Mr. Chriss and Ms. Nicholls from HQIU, as well as Ms. Castro, Mr. Davis, and Mr. Jones from the AG's Office.

Ms. Delp noted the agenda for this meeting included an update regarding the changes made to the Business and Professions Code section (805) peer review reporting process; a discussion about monitoring vertical enforcement (VE) investigations and post accusation cases; a dialogue about the potential changes to the VE process and how those changes would be implemented; and the role of a probation inspector and what functions could be transferred to them. She added that a discussion also took place about changes HQIU has made to resolve its vacancy rate and a review of enforcement statistics.

Ms. Delp added that Ms. Nicholls would discuss the efforts made by HQIU to resolve their vacancy rate issues during her presentation at the full Board meeting.

Ms. Delp stated the improvements to the 805 peer review reporting process were working well and that subpoenas are usually drafted, executed, and served within one week to ten days of the date of the filing of the 805 report. This improvement began on April 24, 2017. Twenty cases have been reviewed overall.

Of the 18 of the 805 reports reviewed statewide, 18 subpoenas were prepared, executed, and served. Ms. Delp stated compliance letters were sent to three facilities requiring a new 805 report to be completed and submitted within five business days, as the original 805 report lacked sufficient detail as required by law. She added that a total of four cases have been reviewed for the filing of a Notice of Violation and Imposition of Penalty for late 805 report submissions. She noted two have been declined and two identified for potential action. A Deputy Attorney General (DAG) has been assigned to assemble the cases for prosecution and five cases have been identified as possible interim suspension orders (ISO).

Ms. Delp stated that to ensure investigations are moving along in a timely manner, participants agreed that a plan is needed to address case inactivity. If after two quarterly case reviews, a case has not progressed, the lead prosecutor will email HQIU executive management and address the issue. She added that this is not to say that HQUI and HQE are not doing these tasks, but with the high vacancy rate, and volume of cases investigated and prosecuted, some activities may take longer than usual, and by taking a team approach to monitor cases, overall case processing times will decrease. She noted that Board staff will revitalize the monitoring of a post accusation report. This report shows what cases have been filed by HQE and are awaiting a hearing. By following up with HQE cases will get set for hearing, which will either lead to resolution through administrative hearing, or settlement of the case.

Ms. Delp added in some instances probation would request the assistance of an HQIU investigator to gather evidence, or interview the probationer when staff suspects a violation of probation has occurred. However, probation staff will now take the lead with gathering evidence needed to support a violation and in doing this, HQIU can focus on investigating open complaints.

Ms. Delp stated that overall the meeting was productive and at the request of Dr. Yip, an enforcement meeting will occur every six months to confer on topics related to enforcement and conducting business in the most effective and efficient manner.

Ms. Delp noted that on July 12, 2017, staff from the Probation Unit as well as staff from First Source Solutions, the Board's approved vendor that manages the biological fluid testing program, gave a presentation to all DAGs from HQE. She noted the presentation provided an overview of probation protocols and policies concerning biological fluid testing. Probation staff continues to take immediate action when a licensee has violated his or her probation. Ms. Delp noted that as of July 3, 2017, a total of 52 petitions to revoke probation and eight accusations and petitions to revoke probation have been transmitted to the AG's Office during fiscal year (FY) 16/17, and the total number of cease practice orders issued was 35, which is a 150% increase from the prior year.

Dr. Levine requested that at the next meeting, Ms. Delp include a graph that shows what the process is and what changes were made as a result of the July 5, 2017 meeting. She added this would help Members understand what is going to happen and what is different.

Dr. Lewis agreed with Dr. Levine and stated that at prior meetings there had been a graph displayed. The visual display makes it easier to understand the changes and statistics.

Dr. Yip agreed and stated that meeting was set up in like a workshop, with the three entities involved and discussing case connectivity, to ensure everyone was on the same page with how to shorten time frames. He stated that he learned a lot and will have staff show a graph of the changes at the next meeting. He

noted that he had recommended that this same group meet twice a year to discuss current issues. Dr. Yip thanked all parties for their participation and attendance.

#### Agenda Item 5 Update on the Expert Reviewer Program's Training and Recruitment Plan

Ms. Delp stated that since the last Enforcement Committee meeting update, a total of 35 new experts joined the program and two expert reviewer training sessions are scheduled for the Fall. One training will take place in Sacramento on September 28, 2017, and the second will take place in Sylmar on November 2, 2017. She noted that to encourage attendance, a save the date announcement was sent out via email, and there was also an announcement posted on the Board's website. She stated that the previous trainings were conducted on Saturdays, but this time trainings have been scheduled for a weekday with the anticipation that more experts will participate. There are approximately 700 expert reviewers in the program that have not yet attended the training. Ms. Delp noted that if the Board does not see an increase in attendees in the next two training sessions, the program will send out a survey to active experts in hopes of gathering information that will assist the Board in boosting attendance.

Ms. Delp stated that in regard to the expert reviewer recruitment plan, stage two of the plan was scheduled to be completed by Spring, 2017. However, the program did not meet that goal. Stage two consists of placing advertisements about the program into external newsletters, magazines, and giving presentations about the program at hospital staff meetings, continuing medical education events, and special conferences. She noted that preliminary research had been done to obtain costs for placing advertisements into newsletters and magazines. Staff is also exploring the possibility of attending three recruitment events in the Los Angeles area in September and October, and researching more events to attend through the end of 2017. Ms. Delp added that each time Ms. Kirchmeyer speaks to a group of physicians, she asks for experts to join the program and at a recent meeting, three individuals followed up and applied to become expert reviewers.

The Board's Information Systems Branch (ISB), developed a new expert reviewer database called the Consultant Expert Management Program (CEMA). This program combines the Central Complaint Unit's (CCU) medical consultant database with the expert reviewer database into one comprehensive system. In addition to upgrading the older system into a newer platform, this database has the capability of running management reports, thus eliminating the need to track cases in excel spreadsheets. She noted that CEMA should be fully implemented by mid-August 2017.

Ms. Delp added that program staff is working to create a licensed midwife reviewer brochure, similar to that of the physician expert reviewer brochure that was created and shown at the January Board meeting. Staff is exploring the possibility of creating a bi-annual expert reviewer newsletter to provide information to experts about the program and tips for writing a good report. She noted the program sees this as an opportunity to discuss facets of the expert reviewer manual and to highlight the components necessary to write legally sound opinions. The newsletter would also include material such as showcasing information about the differences between simple and extreme departures, an overview of enforcement functions, the role of the expert in this process, and formatting tips to write a clear and succinct document. She stated that if any of the Enforcement Committee Members were interested in contributing an article to the newsletter, it would be a valuable addition, as Member input is quite valuable to help make the project a success.

Dr. Lewis asked if Members are able to attend events that the program staff are participating in, to add the personal connection of a physician, which may have a positive effect on recruitment.

Ms. Delp stated that any Member is more than welcome to join staff at any event, any time. She offered to send the Committee Members the calendar for these events in the different areas, in hopes that Members could to attend an event.

#### Agenda Item 6 Presentation Regarding the Complaint Investigation Office

Ms. Henderson provided a presentation regarding the history of the Complaint Investigation Office (CIO) along with how, when, and why the unit was created. She noted that the unit consists of one non-sworn supervising special investigator and six non-sworn special investigators. Ms. Henderson explained the types of cases CIO investigates, as well as who handles the investigations. She then provided a comparison of differences between CIO, Department of Investigations, and HQIU. She noted that CIO does not work under the VE model, the cases are processed statewide, and are advised what cases CIO could refer to HQIU if needed. Ms. Henderson noted some changes that had taken place since CIO was established in 2014. CIO has begun issuing subpoenas for medical records, arrest reports, and other documents. In addition 820 mental/physical examinations have been processed as part of the investigation process and on occasion, assist the Board's Probation Unit with processing petitions for early termination of probation.

Ms. Henderson noted that the CIO also works on special projects and assignments such as assisting the Board's Licensing Unit with processing case referrals, DCU with locating licensees, as well as obtaining certified court documents for out-of-state discipline cases that have been forwarded to the AG's Office for disciplinary action.

Dr. Levine referred back to the third slide of the presentation where it lists the types of cases the CIO investigates. She noted that at future meetings, perhaps twice a year, she would like to see those case types broken down by the number of cases, in order to understand the nature of the complaints and accusations. This would also help to understand what direction they are moving. She added that she has a personal interest in knowing more about the vaccination exemptions, tracking of how many of those complaint types are received, and how many are for failure to issue an exemption versus the inappropriate issuance of an exemption.

Ms. Henderson stated that she understood and in response to Dr. Levine's vaccination exemption concerns, she noted that currently CIO has seen that patients have been provided inappropriate issuance of exemptions. She noted that these complaints are coming from schools, other physicians, and sometimes from parents where there is a child custody issue.

Dr. Yip asked who is responsible for signing off on closed cases.

Ms. Henderson stated that she reviews all cases and is responsible for signing off on case closures, as they are not reviewed by Ms. Delp, or Ms. Kirchmeyer. She also stated that anytime a case is closed, it is reviewed by the AG's Office to ensure nothing was missed, or to determine if further investigation is needed. Ms. Henderson noted that since CIO does not work under VE, when a case needs to be

transmitted, CIO processes the documents, and submits the transmittal to the Supervising DAG based on the geographical location of the subject physician.

# Agenda Item 7Update on the Opioid Related Death Certificate Information from the<br/>California Department of Public Health

Ms. Kirchmeyer stated that many of the Members may remember that in 2013 Senator Price, who was then the Chair of the Senate Business and Professions Committee, introduced Senate Bill (SB) 62, which would have required coroners to report deaths when the cause of death was the result of prescription drug use. She noted this report would have contained identifying information so the Board could perform an investigation to determine if a physician was inappropriately prescribing. Ms. Kirchmeyer stated that currently the law requires a coroner to report to the Board when he or she received information based upon the findings by a pathologist indicating that a death may be the result of gross negligence or incompetence of a physician. She added that over the last two years the Board has received nine reports from coroner's offices.

Ms. Kirchmeyer stated at that time Senator Price thought that if the coroner did not have to make a determination that a physician was grossly negligent, or incompetent and that the death was related to prescription drugs, it would improve the reporting to the Board and also help identify physicians not following the standard of care. However, due to the fact this bill would have imposed an unfunded mandate, the bill was vetoed.

Ms. Kirchmeyer stated that after the veto of this bill, staff spoke with the Senate Business, Professions, and Economic Development Committee staff about a possible solution. She stated that after these discussions, the Board staff thought that it may be able to find another path to this information. The Board staff contacted the California Department of Public Health (CDPH), who is responsible for collecting all death certificate information. After several months and meetings, the Board signed an Interagency Agreement with the CDPH to obtain information on deaths in 2012 and 2013 related to opioid prescription drugs. Ms. Kirchmeyer noted that this data set used codes that CDPH was using to identify the underlying cause of death and the contributing cause of death in order to identify opioid pharmaceutical related deaths, and in August 2015, the Board received the information for both of those years.

Ms. Kirchmeyer stated that once the data file was received, the Board used the Controlled Substance Utilization Review and Evaluation System (CURES) database to determine who was prescribing to the individuals and also looked at the prescribing practices of the attending physician, or the physician who certified the death. She added that once CURES information was obtained, the reports were sent to experts who reviewed the data to determine if there may be inappropriate prescribing. She noted the Board had one person assigned to this task. Ms. Kirchmeyer stated that all of the reports have now been reviewed, and the Board was working to initiate all of these cases to either begin the process in the CCU by obtaining the medical records or by sending these cases to the field for investigation.

Ms. Kirchmeyer stated that for the two years, 2,692 deaths fell into the categories identified as related to prescription drugs. She noted that of those, 2,256 had a CURES report that needed to be reviewed by a medical expert reviewer. After those reviews, the Board identified 522 cases that needed an investigation opened, concerning a physician who may have inappropriately prescribed. She stated the Board is currently writing letters to request authorization to review medical records.

Ms. Kirchmeyer stated this has been an extensive project and one that still needs a lot of work to complete. However, this process has been invaluable to the Board's role of protecting the consumer and its goal to find proactive ways to investigate. She added that the Board has received very positive feedback from the experts who have been reviewing these cases. One expert stated that although the initial startup process for these cases has been extremely time consuming, it was worth the effort.

Ms. Kirchmeyer added that another expert stated the systematic approach of this project has given the Board a chance to discover who the over-prescribers are, rather than having to wait for specific complaints to be made. The project has been crucial in discovering these providers and protecting vulnerable consumers struggling with addition.

Ms. Kirchmeyer noted that one expert identified some notable findings in all the cases reviewed, which was quite interesting. She commented that the expert stated that there was a group of patients who died from an overdose unrelated to the prescriptions they were receiving from their physician, revealing the use of diverted or illicit drugs. The expert stated another group of patients had received controlled substances from a large number of prescribers and it was unclear whether any of these providers were aware of the patients' use of multiple prescribers. There was also a group of patients whose death was closely linked to the prescribing habits of their primary provider, which was quite common. The experts had found that in general, providers were writing for high-dose opioids in combination with one or more sedating drugs, such as benzodiazepines, Soma, and sleeping pills. The expert went on to state that this is probably the most important lesson from this work; the specific link of patient deaths related to the known risks associated with high-dose opioids, particularly when linked to the concurrent use of other sedating medications. The experts found that in reviewing the CURES report on these providers, it was common to see many other patients receiving the same combinations and who are at risk for harm.

Ms. Kirchmeyer added that the expert recommended that the Board continue to obtain this information from CDPH every year. Ms. Kirchmeyer stated that the Board would be doing that.

Dr. Lewis stated that death certificates must include if the cause of death is opioid related and that sometimes it is not listed as such. There are some cases where the coroner is not a physician and the information is often times hidden on the death certificate, which makes it difficult to extract that particular data for this study.

Ms. Kirchmeyer noted that is true and stated that the Board will not going to capture every single death that occurs related to a prescription drug. She noted that there were several different categories, all drug related that were used when pulling together this information.

Dr. Lewis wondered what type of education about this program could be provided to coroners to encourage them to report appropriately.

Ms. Kirchmeyer stated that she was actually giving a presentation in September to the Coroner's Association and would be happy to bring this subject up during her presentation.

Judge Feinstein asked if there was an unexplained death and a physician cannot sign the death certificate, such that law, in a county that does not have a medical examiner's office, requires an autopsy or further investigation their Sherriff must use a medical examiner to conduct the autopsy.

Ms. Kirchmeyer stated that there was a bill passed last year that requires the pathologist who performs an autopsy to be a licensed physician.

Judge Feinstein asked how far back in time the Board could go with investigating a death certificate.

Ms. Kirchmeyer stated that has been an issue with this project and due to statute of limitations, the Board could only go back seven years.

Dr. Levine asked if CURES was capable of querying by dose; for example, prescriptions greater than so many milligrams, or perhaps even Morphine milligram equivalents (MMEs).

Ms. Kirchmeyer stated that CURES is capable of querying by MMEs, but she was not sure about running a report by dosages. She noted she would look into it and let Dr. Levine know.

Dr. Levine stated that report could be another pathway to assist in finding overprescribing physicians for this project.

Dr. Bholat agreed with Dr. Levine and stated that using a number of 120 pills per prescription might be a good number to use when running the CURES reports.

Dr. Yip asked Ms. Kirchmeyer how many experts are being used for that large number of cases that need to be reviewed.

Ms. Kirchmeyer stated that they are using any of the experts that are available in the pool that the Board has. She noted that this is a large number of cases to be added to an already stressed unit, so experts in different areas are definitely needed for this project.

Ms. Fellmeth thanked the Board and staff for pursuing this project as this information is so very important. She noted that people are dying all over the country due to this prescription overdose epidemic.

Dr. Yip stated that Ms. Kirchmeyer has the Committee Members support in helping any way possible since this is such a big project.

Ms. Kirchmeyer stated that another good thing that came out of the project is that the Board will be able to use this project to create and justify a Budget Change Proposal for staff for this project.

Dr. Levine stated that the Board should back up one step from death, which would be hospital and emergency department admissions, and monitor those who were admitted with a possible overdose.

Ms. Kirchmeyer noted that CDPH does monitor those admissions. They have a heat map on their website that shows by county how many people have been to an emergency department regarding opioid overdoses. She noted that she will work with CDPH to see if that is something the Board can use as another avenue for this project.

Dr. Levine added that it should be noted that California is one of the states with the lowest number of opioid related deaths per hundred thousand people in the country, which means the state is doing something right, even though there is still plenty to learn.

#### Agenda Item 8 Presentation of Enforcement Statistics

Ms. Kirchmeyer noted that at the last Enforcement Committee meeting, there was discussion about obtaining statewide enforcement statistics. Around that same time, she stated she had been reviewing some heat maps that CDPH was putting out on prescribing and opioid related deaths in the state. After the meeting, she met with Sean Eichelkraut, the Board's ISB Manager, to discuss what reports would be possible. She noted that on pages ENF 8-1 to ENF 8-9 are pages of some sample reports that were put together.

Ms. Kirchmeyer stated the first report identifies complaints received per 10,000 individuals. The color of the counties themselves is based strictly on population per census information. However, the circle within each county is based upon the number of complaints received per 10,000 individuals. The county is based upon the complainant's address or if no address, upon the physician's address of record.

She added that the information on the following page just puts numbers to the actual chart and also adds the number of licensees per county based upon their address of record.

Ms. Kirchmeyer noted that on page ENF 8-4, was a sample of what a map would look like for information based upon the medical service, which is captured based upon the allegations involved and the type of practice of allegation. She stated this is not based upon the physician specialty or board certification, it is based upon the type of procedure that was being performed, based upon the review of the complaint.

She then noted that lastly, on page ENF 8-7, was a sample of information that can be obtained by the allegation, such as in this case, negligence or incompetence. She stated there are several other allegation codes, and this was just a sample.

Ms. Kirchmeyer added that she wanted to provide this information to the Members to determine if this was something they would like staff to work more on in order to put this information on the Board's website. She noted that an individual could go to the Board's website and obtain the heat map with the information. She added that staff could also build a map to identify disciplinary action per capita per county too. She stated that she knew the Members wanted a place to obtain this sort of information and this is the first try in getting some information.

Dr. Lewis stated that the Board should be careful that the information is not misinterpreted by the public and that the information really need to instruct them on how to read it so that it is interpreted correctly.

Dr. Levine noted that the maps in the documents are three levels of information, which does make it a bit challenging to read/interpret. She suggested if staff is going to post these to the website, to perhaps break up the overlays into single layers for ease of understanding.

Dr. Bholat stated that when she first looked at the map as a family physician, she was a bit confused and wanted to clarify that those types shown on the map is not by the specialty. She understands that it is based upon where a type of service may occur and suggested that staff be sensitive to that explanation when putting the maps on the website.

Ms. Kirchmeyer stated that staff would be sure to clarify that it is not the specialty of the physician, but rather what the procedure was.

Dr. Bholat asked who regulates the data on workers compensation.

Ms. Kirchmeyer stated that is not something the Board monitors or asks on the physician survey, and the only way data could be obtained is by requesting a report from the Division of Workers' Compensation (California Department of Industrial Relations).

### Agenda Item 9Future Agenda Items

No future agenda items were provided.

### Agenda Item 10 Adjournment

The meeting was adjourned at 2:28 p.m.

The full meeting can be viewed at www.mbc.ca.gov/board/meetings/Index.html