State of California
Business, Consumer Services and Housing Agency

MEDICAL BOARD OF CALIFORNIA

Board and Committee Meetings
February 5, 6, 7, 2014

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MEDICAL BOARD OF CALIFORNIA
BOARD MEETING SCHEDULE

Embassy Suites
150 Anza Boulevard
Burlingame, CA 94010

February 5 – 7, 2014

Wednesday, February 5

- **1:00 p.m. – 3:30 p.m.** **Panel A (Ambassador Room)**
  (Members: Yaroslavsky (Chair), Bishop, Diego, Lewis, Serrano Sewell, Wright, Yip)

- **3:30 p.m. – 5:00 p.m.** **Committee on Physician Supervisory Responsibilities (Ambassador Rm)**
  (Members: Schipske (Chair), Bishop, Barnard, Bruner, Grivett, Kilmer, Newman, Phinney, Robbins)

Thursday, February 6

- **9:00 a.m. – 12:00 p.m.** **Panel A (Embassy C Room)**
  (*Members: Yaroslavsky (Chair), Bishop, Diego, Lewis, Serrano Sewell, Wright, Yip)*

- **10:30 a.m. – 12:00 p.m.** **Panel B (Embassy A & B Room)**
  (Members: GnanaDev (Chair), Krauss, Levine, Lui, Pines, Schipske)

- **12:00 p.m. – 1:00 p.m.** **Lunch**

- **1:00 p.m. – 2:30 p.m.** **Education and Wellness Committee (Embassy A & B Room)**
  (Members: Yaroslavsky(Chair), Diego, Krauss, Pines, Schipske)

- **2:30 p.m. – 5:30 p.m.** **Full Board Meeting (Embassy A & B Room)**
  (All Members)

Friday, February 7

- **8:30 a.m. – 9:00 a.m.** **Application Review Committee (Embassy A & B Room)**
  (Members: Schipske (Chair), Diego, Lewis)

- **9:00 a.m. – 4:00 p.m.** **Full Board Meeting (Embassy A & B Room)**
  (All Members)

MEDICAL BOARD OF CALIFORNIA

QUARTERLY BOARD MEETING AGENDA

Embassy Suites
150 Anza Boulevard
Burlingame, CA 94010
(650) 342-4600 (directions only)

Thursday, February 6, 2014
2:30 p.m. – 5:30 p.m.
(or until the conclusion of Business)

Friday, February 7, 2014
9:00 a.m. – 4:00 p.m.
(or until the conclusion of Business)

ORDER OF ITEMS IS SUBJECT TO CHANGE.

MEMBERS OF THE BOARD
Sharon Levine, M.D., President
David Serrano Sewell, J.D., Vice President
Silvia Diego, M.D., Secretary
Michael Bishop, M.D.
Dev GnanaDev, M.D.
Howard Krauss, M.D.
Ronald Lewis, M.D.
Elwood Lui
Denise Pines
Gerrie Schipske, R.N.P, J.D.
Jamie Wright, Esq.
Barbara Yaroslavsky
Felix Yip, M.D.

Action may be taken on any item listed on the agenda.

While the Board intends to webcast this meeting, it may not be possible to webcast the entire open meeting due to limitations on resources.

Thursday, February 6, 2014

1. 2:30 p.m. Call to Order/Roll Call

2. Introduction and Swearing in of New Board Member

3. Public Comments on Items not on the Agenda
   Note: The Board may not discuss or take action on any matter raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7 (a)]

4. Approval of Minutes from the October 24 – 25, 2013 Meeting

5. Presentation on Health Care Fraud and Abuse: Preventive Strategies in Program Integrity – Dr. Tarzy, Dr. Heard, and Ms. Gray-Bowersox, Department of Health Care Services

6. Board Member Communications with Interested Parties – Dr. Levine

7. President's Report – Dr. Levine
   A. Committee Appointments

8. Interim Executive Director's Report – Ms. Kirchmeyer
   A. Executive Summary

9. Federation of State Medical Boards – Dr. Levine and Ms. Kirchmeyer
   A. Update on Federation of State Medical Board activities
   B. Approval of Recommendation for FSMB Committee

10. Update on the Transition of Investigators to the Department of Consumers Affairs Pursuant to Senate Bill 304 – Mr. Kidane, Mr. Gomez, Ms. Kirchmeyer, and Ms. Threadgill

11. Enforcement Chief's Report – Ms. Threadgill
    A. Approval of Orders Following Completion of Probation and Orders for License Surrender During Probation
    B. Executive Summary

12. Vertical Enforcement Program Report – Ms. Castro
    A. Program Update
    B. HQE Organization and Staffing

13. Review of Responses to Public Comments and Consideration of Revised Regulatory Language Amending Section 1361 and Adding Sections 1361.5, 1361.51, 1361.52, 1361.53, 1361.54, and 1361.55 to Title 16, California Code of Regulations - Uniform Standards for Substance-Abusing Licensees – Ms. Webb and Ms. Cady

14. Update on Health Professions Education Foundation – Ms. Yaroslavsky and Dr. Diego

15. Update on the Committee on Physician Supervisory Responsibilities

16. Update on the Education and Wellness Committee

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Friday, February 7, 2014

17. 9:00 a.m. Call to Order/Roll Call

18. Public Comments on Items not on the Agenda
    Note: The Board may not discuss or take action on any matter raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting [Government Code sections 11125, 11125.7 (a)].

19. 9:00 a.m. REGULATIONS – PUBLIC HEARING – Ms. Webb
    Physician Assistant Scope of Practice – Medical Services Performable. Amendment of Section 1399.541 of Title 16, California Code of Regulations. This proposal would clarify physician supervision requirements when a physician assistant acts as a first or second assistant in surgery.

20. Update on Physician Assistant Board – Dr. Bishop

21. Update from the Department of Consumer Affairs – Ms. Lally

22. Update on Activities of the Board of Pharmacy – Ms. Herold

23. Update on Prescribing Task Force – Ms. Yaroslavsky and Dr. Bishop

24. Presentation on the *National Association of Optometrists & Opticians v. Harris* Litigation – Mr. Terrazas and Ms. Schneider, Department of Justice

25. Update on Licensing Outreach/Education Program – Mr. Schunke

26. Licensing Chief's Report – Mr. Worden
    A. Executive Summary
    B. Approval of Proposed Resolution of Written Examination Passing Scores – Mr. Worden/Ms.Webb

27. Update on the Outpatient Surgery Settings Task Force and Consideration of Recommendation – Dr. GnanaDev and Mr. Serrano Sewell

28. Update on and Consideration of Recommendations from the Midwifery Advisory Council – Ms. Sparrevohn

29. Consideration of Legislation/Regulations – Ms. Simoes
    A. Status of Regulatory Actions
    B. 2014 Legislation
    C. Legislative Proposal

30. Agenda Items for May 1-2, 2014 Meeting in Los Angeles Area

31. Presentation on Postgraduate Training/Residency Programs – Dr. Nation, University of California, Office of the President

32. CLOSED SESSION (1:00 p.m.)
    Pursuant to Section 11126(a)(1) of the Government Code, the Board will meet in Closed Session to interview candidates for and discuss appointment of an Executive Director

33. OPEN SESSION – Report from Closed Session

34. Adjournment

The mission of the Medical Board of California is to protect health care consumers through the proper licensing and regulation of physicians and surgeons and certain allied health care professions and through the vigorous, objective enforcement of the Medical Practice Act, and to promote access to quality medical care through the Board's licensing and regulatory functions.

Meetings of the Medical Board of California are open to the public except when specifically noticed otherwise in accordance with the Open Meeting Act. The audience will be given appropriate opportunities to comment on any issue presented in open session before the Board, but the President may apportion available time among those who wish to speak.

For additional information, call (916) 263-2389.

NOTICE: The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Lisa Toof at (916) 263-2389 or lisa.toof@mbc.ca.gov or send a written request to Lisa Toof. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.

MEDICAL BOARD OF CALIFORNIA

QUARTERLY BOARD MEETING
Mission Inn
3649 Mission Inn Avenue
Riverside, CA 92501

Thursday October 24, 2013
12:30 p.m – 5:00 p.m.

Friday, October 25, 2013
9:00 a.m. – 3:30 p.m.

MEETING MINUTES

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

Members Present:
Sharon Levine, M.D., President
Michael Bishop, M.D.
Dev GnanaDev, M.D.
Howard Krauss, M.D.
Ronald H. Lewis, M.D.
Denise Pines
David Serrano Sewell, J.D., Vice President
Gerrie Schipske, R.N.P., J.D.
Jamie Wright, Esq.
Felix Yip, M.D.
Barbara Yaroslavsky

Members Absent:
Silvia Diego, M.D., Secretary
Phil Tagami

Staff Present:
Veronica Alva, Investigator
Susan Cady, Staff Services Manager II, Central Complaint Unit
Dianne Dobbs, Legal Counsel, Department of Consumer Affairs
Cassandra Hockenson, Public Information Officer
Kimberly Kirchmeyer, Interim Executive Director
Kathleen Nicholls, Supervising Investigator II
Amy Pikschus, Investigator
Dino Pierini, Business Services Officer
Regina Rao, Associate Governmental Program Analyst
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
Natalie Zellmer, Investigator

Members of the Audience:
Alan Alvord, Division Presiding Administrative Law Judge, Office of Administrative Hearings
Theresa Anderson, California Academy of Physician Assistants
Gloria Castro, Senior Assistant Attorney General, Attorney General's Office
Yvonne Choong, California Medical Association
Zennie Coughlin, Kaiser Permanente
Julie D'Angelo Fellmeth, Center for Public Interest Law
Long Do, California Medical Association
Jack French, Consumer's Union Safe Patient Project
Karen Ehrlich, L.M., Midwifery Advisory Council
Michael Gomez, Department of Consumer Affairs
Dolores Green, Riverside County Medical Association
Awet Kidane, Department of Consumer Affairs
Christine Lally, Department of Consumer Affairs
Khadijah Lang, M.D., Charles Drew Medical Society
Lisa McGiffert, Consumer's Union
Michele Monserratt-Ramos, Consumer's Union Safe Patient Project
Jim Peterson, San Bernardino County Medical Association
Alison E. Price, L.M.
Deborah Rotenberg, Planned Parenthood Affiliates of California
Bob Sachs, P.A., Physician Assistant Board
Suzan Shinazy, Consumer's Union Safe Patient Project
Carrie Sparrevohn, L.M., Midwifery Advisory Council
Taryn Smith, Senate Office of Research

Agenda Item 1 Presentation on Information Technology and Healthcare – Mr. Goldman

Glenn Albright, Ph.D. and Ron Goldman with Kognito Interactive, provided a presentation on interactive training simulations that enable health providers to master their communication and interviewing skills in an effort to change the behavior of patients when the provider interacts with them. Kognito built this program based on research in neuroscience, social cognition, and adult learning theory. This program is an online CME-approved course that teaches doctors and nurses to recognize when a patient's physical ailments are masking underlying substance abuse or mental health disorders and how to use motivational interviewing skills to integrate behavioral health into the treatment plan while building the patients motivation to adhere to it.

Agenda Item 2 Call to Order/Roll Call

Dr. Levine called the meeting of the Medical Board of California (Board) to order on October 24, 2013, at 2:05 p.m. A quorum was present and due notice was provided to all interested parties.

Dr. Levine announced that Agenda Item 18 will be postponed until Friday, October 25, 2013.

Dr. Levine stated that she wanted to take a moment and share with everyone that Dr. Janet Salomonson passed away on September 10, 2013, after a brief illness and after returning from a medical mission she was conducting in South America. She stated that Dr. Salomonson was a very talented plastic surgeon and a valuable member of the Board. She did a lot of charity work with children in Central and South America and across the world. Her charitable work was dedicated to children who had cleft palates and other facial deformities that were remediable with plastic surgery. Dr. Salomonson served on the Board from 2006 to July 2013 and she made enormous contributions to the Board. Dr. Levine noted that for those who would like to make a contribution in memory of Dr. Salomonson, either Faces of Hope or Rotoplast have been designated as the recipients of donations in her memory.

Agenda Item 3 Approval of Minutes from the July 18-19, 2013 Meeting

Ms. Yaroslavsky made a motion to adopt the meeting minutes as is; s/Dr. GnanaDev. Motion carried.

Agenda Item 4 Introduction and Swearing in of New Board Members

Dr. Levine introduced, welcomed, and swore in our three new Board Members: Dr. Howard Krauss, Dr. Ronald Lewis, and Ms. Jamie Wright.

Agenda Item 5 Public Comments on Items not on the Agenda

Public Comment was heard on this agenda item.

Jim Peterson and Dolores Green with the San Bernardino and Riverside County Medical Associations welcomed the Board Members and staff to the city of Riverside on behalf of both Medical Associations. They stated that the Inland Empire has approximately 4,000 practicing physicians and the two medical associations represent a little over 50% of them. However, the Empire is also impacted by a shortage of physicians, so they were very happy when Assembly Bill 1288 passed requiring the Board to give priority to physicians who are applying to work in the medically-underserved areas.

Mr. Peterson and Ms. Greed added that their associations have also held CURES registration and are also offering education to physicians on opioid risk management. They added that

they have a successful health information exchange with about 9 million patient's information in that exchange.

Suzan Shinazy, Consumer's Union Safe Patient Project, stated the Consumers Union would like to work with staff on the new website portal, BreEZe. They are finding it not very user friendly to consumers. Ms. Shinazy stated that several aspects are quite confusing and she believes it will deter people from using the site. She noted that Consumer's Union would be willing to assist in making improvements and offered to test the site and provide feedback to assist in making it more user-friendly.

Dr. Khadijah Lang, President of the Charles R. Drew Medical Society, thanked the Board for what it has been doing and brought a concern to the Board from their members. The concern is being brought forward in hopes to get some resolution on the matter. She stated the Society is noticing a large number of African-American physicians in the Los Angeles area having disciplinary actions taken against their licenses. There is a concern that the investigators are possibly targeting physicians of lower profit margins because they do not have the adequate resources for appropriate defense when accusations are made. They feel that, in the interest of promoting what a great job the investigators are doing, the investigators are targeting physicians that are representing underserved populations with more aggressive pursuits. The Society would like to know how to get statistics on how many African-American physicians have been accused and have had disciplinary actions taken against their licenses over the past five to ten years. If that information is not available by racial breakdown, they requested a geographical breakdown of the Los Angeles area.

Dr. Levine then introduced and welcomed the following individuals: Awet Kidane, Chief Deputy Director, Department of Consumer Affairs (DCA); Christine Lally, Deputy Director of Board/Bureau Relations, DCA; Michael Gomez, Deputy Director of the Division of Investigation, DCA; and Taryn Smith, Senate Office of Research.

Agenda Item 6 Presentation on the Interim Suspension Order Process – Division Presiding Administrative Law Judge Alvord

Dr. Levine introduced and welcomed Division Presiding Administrative Law Judge (ALJ) Alvord. Judge Alvord provided a detailed explanation on the Interim Suspension Order (ISO) process and laws. Judge Alvord began with an update on current activities at the Office of Administrative Hearings (OAH). He stated that the Board's ISOs represent about one third of the ISO cases heard at OAH. Typically, the cases come to OAH via a phone call from a Deputy Attorney General (DAG) who has an ISO that is ready to be filed. These cases have to be given priority on OAH's calendar, so they are put on calendar as quickly as possible. The DAG speaks to a Presiding ALJ or calendar clerk to determine if the date being requested by the DAG for the hearing is available. OAH tries to accommodate the requested date. The required documents are served and filed with the OAH. ISOs are the only cases that are allowed to be placed on OAH calendars without all of the required paperwork.

Judge Alvord explained that ISO cases have three opportunities for a hearing. There is an ex parte hearing that is held within 24-hours' notice, a noticed hearing that can happen with 15-days' notice, and a hearing on the accusation filed after the issuance of an ISO. All of these hearings will receive priority calendaring, unless those timelines are waived by the parties to the matter.

Dr. Levine asked if each request for an ISO involves all three types of hearings.

Judge Alvord stated that some ISO cases may only involve two hearings. The Board has the option to seek an ex parte ISO if it is concerned about public safety and wants to get the hearing on calendar within a 24-hour time frame.

Judge Alvord stated that there are two code sections that deal with ISO cases held before OAH. Business and Profession Code (B&P) section 494 and Government Code section 11529. Under B&P section 494, ALJs can suspend a license or impose licensing restrictions when the licensee has engaged in acts or omissions violating the law or has been convicted of a substantiating crime and permitting the licensee to continue engaging in their licensed practice would endanger the public health, safety, or welfare. In order to issue a suspension or restriction, these requirements have to be met. These cases require 15 days' notice unless serious harm to the public would result before the hearing could be held. In those instances an ex parte hearing request can be pursued. However, if an ex parte ISO is issued, a noticed hearing must take place within 15-20 days.

If the hearing on the ISO does not take place within 20 days, the ISO would dissolve automatically by operation of law. The licensee does have the option to waive time so the hearing can sometimes happen later if there is a waiver. At the ISO hearing, the licensee can be represented by an attorney, have a record made of the proceedings, present affidavits or other documentary evidence, and can present oral argument. B&P section 494 does not have a specific authorization to receive testimony at the ISO hearing.

ALJs are required to make a decision and issue an order within five business days following the closure of receipt of evidence. ALJs often issue orders the same day or within just a few days. The ALJ may suspend the license or impose license restrictions, including biological fluid testing, supervision, remedial training, or other types of practice limitations depending on the evidence and the issues.

The standard of proof in these cases is *preponderance of the evidence*, which is different from an accusation case which requires *clear and convincing evidence*. The decision issued on an ISO is a final decision, not a proposed decision, and it is not submitted to a board/agency for adoption. Under B&P section 494, the ALJ decision, although final, is subject to the filing of a writ in Superior Court.

The ALJs have the flexibility to modify or expand an ISO at any time. After the ISO is issued, the board/agency is required to file an accusation within 15 days and the hearing on the accusation has to be held within 30 days after receipt of the notice of defense. If the board/agency does not comply with these time lines, and there has not been a waiver of time,

the ISO will be dissolved by operation of law. Under B&P section 494, if the licensee does not comply with the ISO's terms, that non-compliance could become a separate cause for discipline that the board/agency might bring against the licensee.

The other code section that relates specifically to the Medical Practice Act (MPA) is Government Code (GC) section 11529. The procedures and requirements of this code section are slightly different than B&P section 494. Under GC section 11529, an ALJ can suspend a license or impose restrictions when the licensee has or is about to engage in acts or omissions violating the MPA or is unable to practice safely due to a mental or physical condition. The Executive Director is required to prove that permitting the licensee to engage in the profession will endanger the public's safety, health and welfare. These cases also require 15-days' notice and also have a provision for an ex parte hearing if serious injury would result to the public before the matter can be heard with the 15-days' notice. The ALJs can and do hear these cases within a 24-hour period. If an ex parte suspension order is issued, the noticed hearing has to be scheduled within 15-20 days. The licensee has to be notified, and the failure of that hearing taking place within those time lines, unless waived, also results in dissolution of the ISO by operation of law.

The licensee's rights at these hearings include the right to be represented by council, to have a record made of the proceedings, to present affidavits or other documentary evidence, and to present oral argument. GC section 11529 specifically allows the ALJ discretion to permit testimony at the ISO hearing. The ALJ will grant the ISO if there is *reasonable probability* that the petitioner will prevail in the underlying action and that the likelihood of injury to the public in not issuing the order, outweighs the likelihood of injury to the licensee in issuing the order. The standard and burden of proof is the same as a preliminary injunction under the Civil Code.

GC section 11529 states the ALJ must issue a written decision within 15 days of the ISO hearing on the accusation and the decision must include findings of facts and conclusions articulating the connection between the evidence and the decision. The Board must file an accusation within 15 days of the issuance of an ISO and a hearing must be held within 30 days of the filing of a notice of defense by the licensee. Once the ALJ issues a proposed decision after the hearing on the accusation, the Board must issue its decision within 15 days after receiving the decision from the ALJ or the ISO can be dissolved.

ISOs issued under GC section 11529 are also final orders and are not reviewed by the Board, but they are subject to review if a writ is filed in Superior Court.

Judge Alvord stated that one of the things that OAH looks for during ISO hearings is press coverage. The ALJs pay close attention to the notices to be sure they were served properly, whether enough time has been given, and they make decisions quickly about whether to allow witnesses to testify or not, since it is a discretionary matter.

Ms. Yaroslavsky asked for clarification between B&P section 494 and GC section 11529.

Judge Alvord stated that the B&P Code section 494 applies to all licensed professionals. GC section 11529 is specifically designed for violations of the MPA.

Ms. Yaroslavsky asked how the Board determines which code section to use. Judge Alvord stated that decision is made by the DAG.

Dr. Lewis asked for clarification on a statement that Judge Alvord had made earlier in his presentation in regards to data that shows that approximately 50% of the cases are settled due to increased settlement authority.

Judge Alvord responded stating that OAH reviewed the number of cases that are filed versus cases that resulted in a hearing and proposed decision and approximately 50% of the cases filed actually go through hearing to decision. OAH has observed in the past six to nine months that many boards have been less willing to deviate from their disciplinary guidelines. This impacts how quickly the cases can get to hearing since more hearings are being held.

Ms. Yaroslavsky asked when Judge Alvord believes the OAH will have a full staff of ALJs.

Judge Alvord stated they are currently recruiting to fill all of the vacancies that OAH is approved to fill. They should be fully staffed within the next three to four months.

Dr. Levine asked for clarification on some terms Judge Alvord used earlier in his presentation. One term being “preponderance of evidence,” another being “clear and convincing evidence,” and the third being “evidence consistent with preliminary injunction.”

Judge Alvord explained that “preponderance of evidence” means that the evidence is more likely than not. This term applies to an ISO issued under B&P section 494. “Clear and convincing evidence” is the standard for a physician in an accusation case when the issue is whether to revoke the license, suspend the license, or put the physician on probation. The evidentiary standard the petitioner must meet is clear and convincing, which is a higher standard. It is very close to a “reasonable doubt” standard that one would see in a criminal case. The language of GC section 11529 says that the standard burden of proof is the same as a preliminary injunction under Civil Code of Procedures section 527.

Dr. Levine stated the Board gets asked why an ISO that is sought is not granted, and asked Judge Alvord to discuss some of the top reasons why an ALJ would not grant an ISO.

Judge Alvord explained that there are several factors that are looked at when an ISO is brought to an ALJ. The ultimate outcome is complete suspension of the license, although many cases do not result in a suspension, but result in practice restrictions. The ALJ’s duty is to weigh the evidence and determine what public protection requires in the short term until the case can be heard on the merits of the accusation. The evidence is limited in those cases based on declarations, documents, and oral arguments. The ALJ does a balancing act of the public safety need versus the physician’s right to practice. The challenge is to guarantee public protection without going overboard.

Mr. Serrano Sewell requested that at a future Board meeting the Members be provided with a breakdown of numbers showing how many ISOs were requested by a DAG and how many were actually granted versus those that were denied.

Dr. Bishop returned to Judge Alvord's prior statement regarding the increasing reluctance on the part of the Board to deviate from the disciplinary guidelines, which may mean the Board is doing a better job. He pointed out, however, that in some instances, by the Board obtaining an earlier settlement, this may assist the Board in monitoring the physician's practice earlier than waiting for a hearing and helps obtain consumer protection sooner.

Judge Alvord stated that the OAH offers opportunities to settle, especially with cases that will take longer. The ALJs routinely set an early settlement conference and offer parties to discuss settlement options with one of the settlement judges. The issue of what authority is given to the DAG in that case is between the Board and the Attorney General's (AG) office.

Public Comment was heard on this agenda item.

Long Do, California Medical Association (CMA), stated CMA's position was that the burden of proof for the ISO process under GC section 11529 is "clear and convincing" evidence, which is a higher standard and the same as during the accusation stage.

Agenda Item 7 Board Member Communications with Interested Parties – Dr. Levine

Ms. Wright reported that she had a meeting with the Charles Drew Medical Society, who brought some concerns to her that were forwarded to the appropriate staff and have also been discussed at this meeting.

Dr. GnanaDev noted that he routinely talks with CMA, but does not discuss Board issues.

Ms. Yaroslavsky reported that she met with staff and the Los Angeles County Medical Association (LACMA) to work on opportunities for further collaboration and engagement in education.

Ms. Pines stated that she also participated in the LACMA meeting with Ms. Yaroslavsky.

Dr. Krauss reported that he had lunch with Senator Lieu on non-Board issues; however, the subject of Senate Bill (SB) 62 was raised. Dr. Krauss asked the Senator if he would be willing to meet with Board staff to discuss new language to get the mechanism to require coroners to report opioid deaths to the Board and the Senator was receptive to having that meeting.

Agenda item 8 President's Report – Dr. Levine

Dr. Levine reported that in her role as President of the Board, on August 12, 2013, she met separately with Senator Lieu, Assemblywoman Bonilla, and Assemblyman Gordon to discuss

SB 304, which is the Board's Sunset Bill. It was passed by the Legislature and signed by the Governor. It authorizes the Board to continue for another four years. In addition, Dr. Levine testified in front of the Assembly Business, Professions, and Consumer Protection Committee on August 13, 2013, on SB 304. Her testimony has been provided to all of the Board Members.

Dr. Levine has met with Ms. Kirchmeyer and the Executive Staff every two weeks to discuss on-going work with the Board to assure that staff has what they need from her and to offer her support and assistance in the efforts to continue to accelerate and improve the performance of the Board.

Dr. Levine noted that in an effort to ensure adequate time for conversation at Board meetings, the Board has implemented a small change in proceedings. In the past, staff has provided verbal reports during the Board meeting. In an effort to provide more time for conversation, questions, and answer, the reports will be written and provided in the Board materials. Key points will be highlighted and statistics will be attached to an executive summary. When the Chiefs provide the Board with their update at the Board meeting, they will focus on those key points and answer any questions, but the full update will now be provided in the Board materials.

Agenda Item 8A Committee Appointments – Dr. Levine

Dr. Levine directed Board Members to their packets for an updated Committee Roster. It was reported that Dr. Diego agreed to Chair the Licensing Committee, which will meet after the first of the year. She added that the new Board Members will be sent the details of what each Committee is responsible for and the frequency of the meetings to find out which Committee each Member would be willing and to serve on in the future. The Application Review Committee is in need of an additional ember at this time and the Special Program Committee is in need of two members.

Dr. GnanaDev announced that Panel B voted to make him Chair and Ms. Pines Vice Chair.

Ms. Yaroslavsky announced that she will continue to be the Chair of Panel A and Dr. Lewis will be Vice Chair.

Agenda Item 9 Interim Executive Director's Report – Ms. Kirchmeyer

Ms. Kirchmeyer directed Members to their packets for the Interim Executive Director's Report. This report includes a staffing report, an administrative update, a BreEZe update and a budget update with the attached documents. Ms. Kirchmeyer stated that at the end of the last fiscal year, the reserve was at 5.4 months, but is expected to be at 4.1 months at the end of this fiscal year.

Ms. Kirchmeyer wanted to update the Board on the BreEZe project. She stated this project is a replacement of the legacy enforcement and licensing databases. This new system went live on October 8, 2013, and there have been a few glitches. At this point, the new system does not have the functionality as originally identified; however, the system is still being worked on and will have

fixes made for the next six to eight months. The Board does expect that the end product will have all the bugs worked out and will be providing both staff and the public a system that meets the needs of both.

Ms. Kirchmeyer stated that at the February Board meeting, the Board will have a presentation by Linda Schneider from the AG's office regarding a recently completed lawsuit entitled the *National Association of Optometrists and Opticians v. Harris*. This lawsuit was filed based upon B&P section 655 and 2556 which prohibits business and financial relationships between optometrists and registered dispensing opticians. The courts upheld the constitutionality of these two sections. While the lawsuit was pending, neither the Board of Optometry nor the Medical Board, who oversees registered dispensing opticians, could pursue enforcement action based upon these sections. However, there is no longer a moratorium against the enforcement of those two code sections. The AG's office is working with several dispensing opticians to see if they will voluntarily bring their business models into compliance. Dr. Levine and Board Executive Staff heard a presentation from Ms. Schneider which fully explained the laws and history on this issue and both believe it would be beneficial for the Members in the future. In the meantime, this lawsuit has been resolved.

Dr. Levine stated, for the new Members, that the Board is responsible for the oversight of the registered dispensing opticians and enforcement actions are under the Board's purview.

Ms. Kirchmeyer announced that the Board has worked with Purdue to obtain a list of their physicians in region zero. The Board has also received a list of CVS physicians who they suspect may be overprescribing. Staff has been analyzing those lists and determining the appropriate action for the future. Both lists will be treated as complaints and are considered confidential and will not be provided to anyone. As the data is analyzed, it is being determined if these physicians are physicians the Board is already aware of or if a new complaint needs to be opened and reviewed for possible disciplinary process.

Ms. Kirchmeyer noted that she and Board staff have a meeting scheduled October 31, 2013, with the California Department of Public Health (CDPH) regarding the implementation of SB 304 and the new adverse event reporting for ambulatory surgery centers or outpatient surgery settings. Staff will also discuss with them some interpretations of law regarding outpatient surgery settings to ensure everyone is on the same page. A discussion about the adverse event reports that CDOH has received within that past year will also take place.

At the last Board meeting, Ms. Kirchmeyer had reported that she and the Board staff had met with the California Correctional Health Care Services (CCHCS) regarding the tubal ligation issue and the investigative report. She stated that another meeting was held with the CCHCS to further discuss this issue. Since that time the Board has received a list of patient inmates and staff will be looking into those cases; however, that information will be kept confidential.

Ms. Kirchmeyer announced that the Board has been asked by the Assembly Business, Professions, and Consumer Protection Committee staff to provide an "Enforcement Camp," which will be basically "Enforcement 101." This camp will take place on Wednesday, November 6, 2013. The

Board feels it is very important for the legislative staff to understand fully how the enforcement process works when reviewing and analyzing any bill that would pertain to the Board.

Public Comment was heard on this agenda item.

Yvonne Choong, CMA, commented on the BreEZe update in regards to the physician renewal system being taken off line. CMA has received some calls from physicians who had been caught in the system transition. The California Hospital Association (CHA) has also received some calls from physicians with the same issues. She stated that in conversations with Board staff, she brought to staff's attention the issue of how physicians are notified about such changes. She understands that the physicians were emailed and that the notification of the changes was posted on the Board's website. She noted that CMA and CHA are offering their assistance in publicizing any future changes that will affect physicians.

Agenda Item 10 Request Approval to Obtain an Attorney General Legal Opinion Regarding Medical Assistant Scope of Practice – Ms. Webb / Ms. Kirchmeyer

Ms. Kirchmeyer stated that on June 26, 2013, a letter was received from Stephanie Nunez, Executive Officer of the Respiratory Care Board (RCB) requesting the Board revise its Frequently Asked Questions (FAQ) for medical assistants. Ms. Nunez requested that the revision include a question and answer stating that medical assistants cannot perform any level of pulmonary function testing. Based on this letter, the Board requested a medical consultant review the letter and request from Ms. Nunez. The medical consultant did not agree with this request stating that medical assistants could perform some of the testing that the RCB was saying they could not. Therefore, the Board's legal counsel, Ms. Webb, reviewed the matter. Upon Ms. Webb's review, it was agreed that a legal opinion from the AG's Office should be sought. Since this issue is between two boards under the DCA, the opinion would be more appropriate coming from the AG's office.

Ms. Webb referred the Board to the memo on this agenda item in the Board materials. She stated that the memo identifies the statutes and regulations that apply to medical assistants. Ms. Webb stated that upon review, it appears that the basic screening test for pulmonary function are similar to other functions that medical assistants are specifically permitted to do. Ms. Webb believes that if a medical assistant can perform the basic level pulmonary function screening tests safely and appropriately it would create a barrier to care to force a patient to go to a respiratory care therapist, especially when there is no specific prohibition in the statutes or regulations against them doing this testing.

Ms. Webb stated that if Members agree that the basic level of screening cannot be done by a medical assistant then staff should be instructed to put the proposed FAQ on the Board's website. However, if the Members want to have this reviewed and get an opinion from the AG's Office, then there needs to be a motion to that affect by the Board.

Dr. GnanaDev stated that he does not feel that basic screening tests are any more difficult than a basic electrocardiogram, and believes that the medical assistant should be able to perform these tests, under the supervision of a physician, physician assistant, or nurse practitioner.

Dr. Levine agreed with Dr. GnanaDev and stated this is standard practice in every primary care office for management of mild and moderate asthma.

Ms. Yaroslavsky commented that the Board has always had the rule that if one has been trained to do it and it falls within the parameters of supervision or direct instruction from a physician that it can be done.

Public Comment was heard on this agenda item.

Dr. Lang, Charles Drew Medical Society, asked if this would just be a legal review or if physician opinion would also be sought.

Dr. Levine, stated that should the Board determine a legal opinion is needed, the matter would be referred to the AG's Office for review and it would need to analyze the matter as necessary.

Deborah Rotenberg, attorney with Planned Parenthood Affiliates of California, requested that the Board review its FAQs regarding medical assistants. Planned Parenthood believes the FAQs are severely outdated and are noticing that other regulatory entities are weighing in on the scope of practice for medical assistants in a way that may be inconsistent with what the Board would support. Planned Parenthood employs medical assistants, trains them in their clinics, and relies on them. Planned Parenthood strongly supports the Board revisiting the FAQs regarding medical assistants.

Ms. Yaroslavsky made a motion to refer this matter to the AG's Office to seek a legal opinion; s/Wright. Motion carried.

Agenda Item 11 Federation of State Medical Boards – Federation of State Medical Boards – Dr. Levine / Ms. Kirchmeyer

Ms. Kirchmeyer reported that in July, the Federation of State Medical Boards (Federation) Board of Directors approved its final policy entitled *"Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain."* This new policy will supersede their 2004 policy. It provides guidelines to help physicians who prescribe opioid analgesics to do so in full compliance with state and federal regulations, accepted clinical practice, and in a manner that is safe and reduces risk. The Federation also adopted a policy entitled "*Model Policy on Data 2000 and Treatment of Opioid Addiction in the Medical Office."* These two policies provide important guidance for clinicians as the medical community continues to face the challenges of treating chronic pain while confronting the public health threat of opioid misuse, abuse, and addiction. The Federation sought input from state boards' experts in pain medicine and a diverse group of stakeholders and national professional organizations. The Board's Prescribing Task Force will be reviewing these two newest policies when revisiting the Board's pain management guidelines.

The Federation also continues to work on the interstate compact for medical licensure and on October 7, 2013, a press release was issued regarding moving forward with eight consensus principals used to shape a model compact. They established an expanded interstate compact task force made up of representatives from state medical boards, the Federation, and consultants from

representatives in expertise in state compacts. They have finalized a set of recommendations for the initial framework for an interstate medical licensure compact for states to provide input. In general, these compact recommendations envision a compact model that would maintain state authority and control, establish high standards for physician eligibility, ensure a well-coordinated and fairly-applied system of oversight in discipline. An effective interstate compact must include a cooperative system of information sharing and rapid adjudication of disciplinary issues between states. The Federation is beginning the drafting phase for a compact.

Dr. Levine gave a brief description of what an interstate compact is for the new Members, so they would understand why it is so important to get the interstate compact completed.

Ms. Kirchmeyer continued stating that the Federation is working on a newly-introduced federal bill. On September 10, 2013, representatives Devin Nunez and Frank Paloni introduced HR 3077, entitled "*The Telemedicine for Medicare Act of 2013*." The bill allows a Medicare provider licensed in one state to treat any Medicare beneficiary in another state via telemedicine without requiring additional state licensure where the patient is located. Under this legislation, the provider would remain under the jurisdiction of the state medical board where he/she is licensed for the purposes of discipline, effectively eliminating the requirement for the physician to be licensed where the patient is located. To date, the bill has 17 bi-partisan co-sponsors and now that the Federal Government shutdown has ended, it is expected there will be a strong push for the House of Representatives to pass this legislation. Ms. Simoes and Ms. Kirchmeyer will be working with the Federation to reach out to Congressman Nunez's office and other California offices on this issue to help them understand the issues surrounding enforcement under this model.

The Federation also has a notice and is seeking resolutions by February 24, 2014 for their annual meeting. If any Member has any resolutions they would like to submit, let Ms. Kirchmeyer know so the idea can be discussed, developed, and put forward at the February Board meeting for approval.

Dr. Levine wanted to clarify that one of the challenges for a physician is that the standard has always been that the practice of medicine is where the patient is and every state has varying requirements around what constitutes safe medical practice and one concern is jurisdiction shopping. The state that has the fewest requirements and the weakest enforcement would be the state physicians would go for licensure. If there are no prohibitions against practices across state lines, it really binds the hands of state in terms of ensuring that physicians are practicing up to the standards that the state has promulgated through legislation.

Ms. Kirchmeyer stated that the Federation is seeking nominations for elective offices. The information has been sent out to all Members regarding these positions and to date, Ms. Kirchmeyer has had no responses from anyone who would like to run for office at this time. The Federation is also seeking individuals who are interested in serving on Committees within the Federation. Two Members have stated their interest in being appointed to a Committee. Dr. Levine and Dr. Krauss are both interested in being appointed to the Ethics and Professionalism Committee. In addition, Dr. Krauss is interested in being appointed to any special committee that may be convened in relation to advocacy, government affairs, and policy. Ms. Kirchmeyer asked for a motion to approve the preparation of a letter of recommendation and support for Drs. Levine and Krauss to the Ethics and

Professionalism Committee and Dr. Krauss to any special committee established by the Federation in those areas.

Dr. GnanaDev made a motion; s/Dr. Yip. Motion carried.

Agenda Item 9B Consideration of 2014 Board Meeting Dates

Dr. Levine referred Members back to Agenda Item 9B to discuss and confirm the 2014 Board meeting dates. The first two meeting dates were approved at a previous Board meeting. The proposed dates for the end of 2014 are July 24-25, 2014, in Sacramento and October 23-24, 2014, in San Diego. Dr. Levine asked for a motion to approve the July and October dates.

Dr. GnanaDev made a motion to approve the dates as stated; s/Ms. Yaroslavsky. Motion carried.

Agenda Item 12 Update on the Enforcement Committee – Dr. GnanaDev

Dr. GnanaDev stated that the first agenda item was a presentation by Ms. Kirchmeyer, Mr. Gomez and Mr. Kidane regarding the transition of the Board's investigators to the Division of Investigation (DOI) at DCA per SB 304. Mr. Gomez provided a chronology of the transition plan and both he and Mr. Kidane indicated they would be reporting progress of the transition at each quarterly Board meeting. The Board was provided charts and an explanation on how the transition will take place.

Dr. GnanaDev stated the Committee then received a presentation by Ms. Sweet, which included the accomplishments of the Enforcement Program over the past six years. Despite the numerous obstacles, such as furloughs, hiring freezes, and other challenges, the Enforcement Program had some impressive productivity gains, including a 351% increase in criminal referrals, 100% increase in license suspensions and restrictions, a 39% increase in completed investigations and a 36% increase in referrals to the AG's Office. In addition, there was a decrease in investigation time lines by 15%.

Dr. GnanaDev stated the Committee agenda item to discuss suggested improvements to the Enforcement Program and review of Member survey results, was deferred to a future meeting due to the transition of the investigators to DCA. Then the Board can make specific suggestions and solutions for improvement.

Ms. Sweet also provided a progress update on the Prescribing Strike Force, Operation Rx. Operation Rx is currently investigating 27 cases, and since the last Board meeting, four physicians and one physician assistant have been arrested, with criminal charges pending. Staff has completed three search warrants, fifteen undercover operations and procured over 2000 physical prescriptions as part of these investigations. There are numerous search warrants in the planning stages. Ms. Sweet explained how overprescribing allegations are fraught with challenges because of the sheer volume of materials needed for prosecution. Ms. Sweet also gave an update on the next Expert Reviewer Training, which is scheduled for Saturday, November 2, 2013, at UC San Diego. Ten hours of CME will be provided to participants who attend the training and complete the sample expert opinion. Dr. GnanaDev encouraged Board Members to attend this meeting if at all possible.

The Committee was then provided an update on the Probation Monitoring Unit by Ms. Cady. Currently there are 561 physicians on probation. During the past two fiscal years, 58% of the probationers have successfully completed probation. The most common violations leading to probation are gross negligence and incompetence, including inappropriate prescribing violations. Ms. Cady gave a presentation that focused on several conditions most commonly ordered as part of probation, including the clinical training requirement and biological fluid testing.

Dr. GnanaDev requested Ms. Kirchmeyer, Mr. Kidane, and Mr. Gomez provide a brief update to all Board Members on the presentation that was given at the prior day's Enforcement Committee meeting. Ms. Kirchmeyer provided information in regards to how the transition of the Board's investigators is going to impact the Board, its processes, and vertical enforcement. The Board Members were asked to reference the documents found under the Enforcement Committee section of the Board materials. Mr. Kidane and Mr. Gomez went over the transition plan and provided some background on the DOI.

Public Comment was heard on this agenda item.

Lisa McGiffert, Consumer's Union Safe Patient Project, stated that staff had recommended during the Sunset Review process that the Board accept a proposal for physicians who are on probation to notify and inform their patients when they are on probation. The Board did not agree to that recommendation, but Consumer's Union believes it was a strong recommendation and the Board should reconsider its decision. They have discovered that in the regulations, everyone gets informed except the patient. The hospital or any facility where the physician works, the chief of staffs, etc., are notified, but the patients are not. Consumer's Union is finding that typically consumers do not know who the Board is and do not know to check the Board's website for the status of their physician, especially if it is someone they have seen regularly for some time. Consumer's Union is recommending that the Board amend the guidelines to set a standard condition of probation that requires physicians, who continue to see patients, to be required to inform the patients in some way that they are on probation. Consumer's Union is open to working with the Board to find ways to make that happen. They would like this issue to be put on the next meeting agenda for discussion.

Agenda Item 13 Enforcement Chief's Report – Ms. Threadgill

Ms. Threadgill asked for a motion to approve fourteen orders following completion of probation and three orders for license surrender during probation.

Ms. Yaroslavsky made a motion to approve the orders; s/Dr. GnanaDev. Motion carried.

Ms. Threadgill referred the members to the Board materials for the Chief of Enforcement's Executive Summary that included an update and observations made regarding statistics. She asked Members if there were any questions in regards to the summary.

Ms. Threadgill stated that on October 3, 2013, she attended Dr. Yip's "grand rounds" presentation at the University of California, Los Angeles - Harbor facility. Following the presentation, Ms. Threadgill took Dr. Yip to the Cerritos district office to talk with staff members.

She then reminded the Board that at the July Board meeting she reported that the DCA was doing an audit of the Board's evidence accounts. The DCA concluded the audit and has provided staff the opportunity to respond to the draft report. Staff will respond by the end of October and the final report will be provided to the Members.

Ms. Threadgill announced that the Board is currently in the process of advertising to fill the non-sworn investigator positions in the Central Complaint Unit. These positions were received as part of the Consumer Protection Enforcement Initiative (CPEI).

This new non-sworn unit is designed to relieve sworn investigators from high caseloads. It is anticipated that this unit will result in fewer cases being sent to sworn investigators for investigation, thus, lowering investigator caseload. Historically, it has been found that lower caseloads result in reduced case time lines.

Ms. Threadgill then introduced and thanked the investigators who were in attendance at the Board meeting, which included Kathleen Nichols, Supervising Investigator II and Investigators Natalie Zellmer, Amy Pikschus, and Veronica Alva.

Dr. Levine read from Ms. Threadgill's Executive Summary report the following improvements this fiscal year in comparison to fiscal year 11/12:

- Average number of days from the complaint received by the Board to complaint closed or sent to investigation decreased by 23 days; and
- Average days from receipt of complaint, to investigation, to closed or referred for action decreased by 106 days.

Dr. Yip thanked Ms. Threadgill for attending his presentation and for taking him to a district office where he learned a lot and he encouraged other Board Members to do this in the future at some point.

Agenda Item 14 Vertical Enforcement Program Report – Ms. Castro

Ms. Castro, Senior Assistant Attorney General, introduced herself for the new Board Members and stated the Health Quality Enforcement Section (HQES) of the AG's Office is charged, legislatively, to investigate and prosecute disciplinary actions of the Board's licensees.

Ms. Castro announced that a new supervising DAG, Judith Alvarado, was hired in the Los Angeles office. She added that HQES hopes to fill the Supervising DAG in Sacramento soon. The HQES continues to fill vacancies statewide.

Ms. Castro reported that she and Ms. Kirchmeyer continue to have their bi-weekly meetings to discuss any issues on an ad-hoc basis and have an open line of communication. Ms. Kirchmeyer knows that she can contact them anytime, and will get a response quickly.

This same level of interaction also takes place with Ms. Threadgill and Ms. Sweet. They often discuss cases and dispute cases on different issues and are always available to each other.

The next quarterly meeting between the Board and HQES staff is scheduled to take place on November 7, 2013. In response to the Board's request for the AG's Office to have more uniformity between cities in how the vertical enforcement model (VE) is administered, the lead prosecutors meet once a month to discuss issues and the SDAGs meet every other week.

HQES continues to reconcile unpled cases and is providing a list of them on a monthly basis to Ms. Kirchmeyer. HQES staff works with Board staff to reconcile lists to make sure all cases are accounted for and moving through the process. They provide statistics as needed and requested to assist the Board.

Ms. Castro reported the HQES is excited to pair up with the DCA and they will do everything possible to ensure a seamless transition. Ms. Castro stated that the VE model has been institutionalized and is no longer a pilot. Over the past seven years, the AG's Office and the Board have refined what it means to manage cases through the VE process so cases are done efficiently. Throughout this process, it has been envisioned that the AG's Office is in charge of directing, but not supervising, the investigators. They are looking forward to the joint assignment between the DCA investigators and the DAGs. They have had a long history of positive interactions with the DOI, as HQES works with DOI investigators already. Ms. Castro stated that Mr. Gomez and she are very cognizant of the fact that the Board will hold them accountable for the performance metrics.

Dr. GnanaDev thanked Ms. Castro for the willingness to work together and understanding the Board's expectations.

Agenda Item 15 Update on Licensing Outreach/Education Program – Mr. Schunke

Mr. Schunke stated that he is the Board's liaison to the teaching hospitals, clinics and medical schools around California. He assists medical students in learning how to get licensed. His outreach covers two venues. During orientation, he provides general oversight of the licensing program and process in California. This occurs from the middle of June to the beginning of July. Throughout the rest of the year, Mr. Schunke travels to teaching hospitals around the state together with an individual who can perform fingerprinting, a photographer, and a notary to assist the residents start the licensing application process. He meets with approximately 2,200 residents who are just starting the application process and conducts an initial review of their application to be sure that the application is filled out correctly.

Ms. Yaroslavsky recognized and thanked Mr. Schunke for all that he does as it assists in many different aspects of the licensing program and keeps applications coming in correctly, which allows the licensing staff to complete applications in a timely manner.

Agenda Item 16 Licensing Chief's Report – Mr. Worden

Mr. Worden began by thanking his staff for continuing to do an outstanding job this quarter. Currently, licensing has four vacant positions, which have been advertised. Interviews have been done to fill several of these positions.

Mr. Worden referred Members to the Board materials as he briefly went over the Licensing Program statistics. He stated that the licensing unit did not meet its goal performing initial reviews of all physician applications within 45 days of being received for one week during the thirteen-week quarter, nor did the mail get processed as timely as normal. The number of staff working on BreEZe testing had a significant impact on not meeting the desired goals.

Mr. Worden reported on how the BreEZe system has affected the Licensing Program. BreEZe went live on October 8, 2013, at which time the licensing subject matter experts started testing the system to determine if the system was stable enough to have staff begin working in the system. One problem that has been identified is that when the data transfer took place several fields did not transfer correctly and/or completely. Staff has been working to get the missing information added and/or corrected. The Information Services Branch (ISB) staff has offered outstanding service and assistance since the go live date. The Consumer Information Unit (CIU) is also doing an outstanding job since the go live date, as the phone calls and emails have increased tremendously.

Agenda Item 17 Update from the Outpatient Surgery Settings Task Force; Consideration and Possible Action – Dr. GnanaDev/Mr. Serrano Sewell

Dr. GnanaDev reported that on September 30, 2013, he and Mr. Serrano Sewell met with staff in Oakland to discuss the Outpatient Surgery Settings (OSS) Program. There were two main objectives: 1) review staff's proposed revisions to the OSS website pages; and 2) review current statutes and regulations regarding the OSS accreditation requirements for possible statute changes to enhance consumer protection.

The Task Force Members reviewed staff's proposed changes to the Board's OSS Program website pages and made some suggestions to provide further clarity to consumers. Staff is working on these recommendations.

The Task Force Members reviewed Health and Safety Code (HSC) section 1248.15 and identified some subsections that may need to be revised through a statute change and/or clarified through regulations. The Task Force Members recommended deleting the least stringent method of qualifying for accreditation, since this method of qualification does not provide adequate consumer protection.

The Task Force Members also reviewed HSC section 1248.35 and identified some subsections that may need to be revised through a statute change and/or clarified through regulations. The Task Force Members are recommending unannounced inspections of the OSSs.

The Task Force Members reviewed California Code of Regulations (CCR), Title 16, Division 13, section 1313.4 and determined that two of the subsections are no longer valid as a result of recent statute changes. This section needs to be amended accordingly.

The Task Force Members are also considering requiring the initial accreditation of an OSS to be for no more than two years. This would require a statute and/or regulatory change.

The Task Force Members identified that consumer protection may be enhanced if all accredited OSSs have mandatory peer review of procedures performed, regardless of how many practitioners are at an OSS.

The Task Force Members reviewed the issue of requiring all physicians who perform procedures in an OSS to have hospital privileges at a local community hospital for the same procedures that are being performed at the OSS. The Task Force Members do not believe this is necessary. Many physicians who currently use an OSS do not have hospital privileges as they do not perform procedures that require stays for longer than 23 hours. The proposed new peer review requirement, requiring all physicians to be subject to peer review on a regular basis, and the deletion of the third method of accreditation would address these concerns.

Mr. Serrano Sewell thanked the staff for convening this meeting at a mutually agreeable time and location. He and Dr. GnanaDev had a good discussion about what the next steps should be. The first and foremost step should be to conduct an interested parties meeting. This meeting is crucial as it will allow stakeholders to voice their concerns. Once those concerns are heard, the Task Force may change its position, but these are the initial thoughts. Ms. Serrano Sewell stated he is concerned about the number of required inspections and does not feel it is satisfactory. There are some OSSs that have good internal standards and could serve as a model for others to follow.

Mr. Serrano Sewell stated the Task Force Members reviewed the issue of requiring all physicians who perform procedures in and OSS to be board certified by an American Board of Medical Specialties (ABMS) affiliated board in the specialty of the procedures being performing at the OSS. Currently many physicians who are very well trained and qualified to perform procedures in OSS are not board certified. The Board does not license physicians by specialty or require certification to become licensed. The proposed new peer review requirement, for all physicians to be subject to peer review on a regular basis, would help address concerns regarding physicians safely performing procedures in an OSS.

Ms. Yaroslavsky thanked both Mr. Serrano Sewell and Dr. GnanaDev for the work they are doing on this important issue. She is concerned that since the Task Force determined that physicians do not need to have privileges at a hospital, that doctors who need to be able to transfer patients from an OSS will not be able to if they do not have transfer privileges.

Dr. GnanaDev stated that to be accredited, they have to have a transfer agreement with the hospital or have a transfer agreement with a physician with hospital privileges who can take care of that patient when they are transferred. Without the transfer agreement with the hospital or the physician, an OSS could not be accredited by the Board's accrediting agencies based upon the recommended changes.

Another concern that Ms. Yaroslavsky had was in not requiring board certification by an ABMS board.

Dr. GnanaDev responded by stating there are two different areas where that becomes difficult to implement if the Board were to make this requirement. One area is in rural areas, where procedures in the hospitals do not even require board certification. They base the physician's qualifications on

training, experience, and peer review. The second area is that many physicians practice area do not require board certification or hospital privileges, as there is no reason for them to do so because they are covered by their agreement with a hospital and/or their agreement with other surgeons. If the physician does not have board certification, it does not mean that they do not have the qualifications to perform a procedure.

Ms. Webb stated that in current law with regards to accreditation requirements, there are three possibilities currently: 1) to have a written transfer agreement with a local hospital; 2) to permit surgery only by a licensee who has admitting privileges at the local hospital or a written agreement with a physician who has admitting privileges; and 3) to submit a detailed procedural plan for handling medical emergencies to the accreditation agency at the time of accreditation (which the Task Force is proposing to be eliminated). The accreditation agency has to approve the procedural plan, and no reasonable plan shall be disapproved by the accreditation agency.

Dr. GnanaDev stated that the Task Force felt that the third option is a weak option that does not provide consumer protection and that is why the recommendations is to eliminate it.

Dr. GnanaDev asked for a motion to authorize staff to hold an interested parties' meeting regarding proposed changes to statutes and regulations impacting the OSS Program.

Ms. Yaroslavsky made a motion to approve the Task Force recommendation to hold an interested party meeting; s/Dr. Yip. Motion carried.

Dr. GnanaDev then asked for a motion to authorize the OSS Task Force Members, after the interested parties' meeting, to direct staff to draft proposed language to amend current statutes regarding OSSs to improve consumer protection.

Ms. Yaroslavsky made a motion to authorize the Task Force to direct staff to seek legislative changes; s/ Dr. Krauss. Motion carried.

Dr. GnanaDev also asked for a motion to authorize the Task Force Members to direct staff to draft proposed language to amend existing regulations and/or draft new regulations within the California Code of Regulations, to further clarify existing and/or new statutes pertaining to OSSs.

Ms. Yaroslavsky made a motion to authorize the Task force to direct staff to begin any regulatory process needed for regulation amendments or additions; s/ Dr. Krauss. Motion carried.

Lisa McGiffert, Consumer's Union Safe Patient Project, stated they look forward to working with the Board on this subject and participating in these meetings. They would really like to see the full history of the OSSs online for people to review. They understand that there is no legal authority to do that, but some of the clinics do provide that information, and for those that do, they would like to see that information posted on the Board's website. They would also like to see the Board's website to be the place where information is collected about the OSS, such as adverse events relating to the OSS and also links to disciplinary actions of any physicians present in the OSS. With regard to the OSSs, they believe that the people operating these clinics need to be board certified. On a

consumer's level, that shows a certain level of competency. In addition, they believe that there are some things that these OSSs should have to report to the Board and to the accrediting agencies, including deaths occurring in the OSS, transfers to hospitals, and other significant things, such as adverse events. They would also like to see some support from the Board to change the law that requires OSSs to submit information to the Office of Statewide Health Planning and Development (OSHPD), so that the volume of information and the types of procedures being done in the OSSs is being collected.

Dr. GnanaDev stated that there were several other issues that were discussed at the Task force meeting, including being transparent. The Task Force wants to be sure that all the information about the OSSs as authorized by law will be on the website. The Board will likely be the only entity that posts that much information on its website and he wants to make sure it is very transparent.

Dr. Bishop agrees that safety in these OSSs is very important; however, he believes that one misconception is that if someone is board certified there can be a guarantee of patient safety. He noted that most of the physicians that are disciplined are board certified. That alone does not give consumers any measure of certainty. The key here is that the accreditation agencies do what the Board and the law requires of them in order to ensure the physicians in an OSS meet the high standards in terms of their training and skills.

Dr. Levine noted that the move from board certification to maintenance of certification will in the future provide a much better guarantee of continued competence and professionalism.

Agenda Item 19 Update on Physician Assistant Board – Dr. Bishop/Mr. Sachs

Dr. Bishop introduced Mr. Bob Sachs, President of the Physician Assistant (PA) Board, and thanked Mr. Sachs, Mr. Mitchell, and the staff from the PA Board for their warm welcome and help during his first PA Board meeting.

Dr. Bishop reported that the most recent activity at the PA Board was to look at the Manual of Disciplinary Guidelines which was updated in 2007. The Board staff identified changes that needed to be made to update the guidelines. Additionally, the uniform standards for substance abusing healing arts licensees (SB 1441) are to be incorporated in the guidelines. At the August 2013 meeting, the PA Board approved the proposed regulatory language and directed PA Board staff to proceed with the rulemaking process.

The PA Board's strategic plan was last updated in November, 2009. The DCA has encouraged boards who have not updated their plans recently to do so. PA Board Members and staff will be working with the DCA SOLID training office to review and update the plan. Currently, SOLID staff is conducting a stakeholder survey and will interview PA Board Members to assist in identifying the PA Board's strengths, weaknesses, opportunities, threats and future trends impacting the PA profession.

Dr. Bishop continued his update stating the PA Board recently updated its "What is a PA?" consumer information brochure. Additionally, a regulatory proposal to implement AB 2699, free health care events requirements as required by the B&P section 901, was approved by the Office of

Administrative Law in August, 2013 and became effective October 1, 2013. Dr. Bishop added that the DCA has rolled out the new BreEZe system for health care boards. The PA Board has converted all license and enforcement records to BreEZe and began using the system on October 8, 2013.

Agenda Item 20 Consideration of Regulatory Proposal to Revise Physician Assistant Scope of Practice (CCR, Title 16, Division 13.8, Section 1399.541) – Dr. Bishop / Mr. Sachs

Dr. Bishop referred the Board Members to agenda item 20 in the Board materials. The proposed language to amend Title 16 of the CCR section 1399.541 regarding the personal presence of the physician, while a PA acts as a first or second assistant in surgery, is included. In 2011, concerns were raised that the existing regulations did not reflect current medical community standards. Under the existing regulation, the PA may act as first or second assistant in surgery under the supervision of a supervising physician. To reflect the current community standards, this proposal would clarify that a PA may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the PA. "Immediately available" will be defined as able to return to the patient without delay upon the request of the PA, or to address any situation requiring the supervising physician's services. In July 2013 the PA Board staff shared the revised draft language with the Medical Board staff and legal counsel to anticipate any concerns the Medical Board Members may have. None were identified.

At the August 2013 PA Board meeting, PA Board Members voted to approve the proposed language and submit the proposal to the Medical Board. It should be noted that the proposed language is similar to and modeled after a recent Medical Board regulatory proposal regarding physician availability for mid-level practioners, including PAs, to perform elected cosmetic procedures, 16 CCR section 1264.50. This regulation was approved by the Medical Board earlier in the year. The term "immediately available" will be standardized, familiar and understood by supervising physicians and PAs.

Dr. Bishop noted that one non-substantive change will need to be made to the text. This proposal should strike the word "approved" as a modifier to the supervising physician. This change is made to reflect a 2002 change of the law permitting any licensed physician to act as a supervising physician for a PA. This change would only conform to existing law.

Dr. Bishop stated that consumer protection is assured because the term "immediately available" is precisely defined and will ensure that the PA is appropriately supervised. Additionally, amending the regulation will not reduce consumer protection because the supervising physician will be immediately available to provide assistance to the PA. Ultimately, the supervising physician is responsible for the care that is provided by the PA.

Dr. Bishop made a motion, on behalf of the PA Board, that the Medical Board consider this regulatory proposal and direct staff to begin the rulemaking process to adopt the proposed language; s/Ms. Yaroslavsky.

Mr. Sachs reported that the PA Board did what the Medical Board Members asked them to do last year, which was to discuss the language with Medical Board attorneys and staff. He stated that what is before the Board Members today is the outcome of those discussions. He believes that the proposed language is very workable and still protects the consumer. The language still requires the supervising physician to delegate the procedures that the PA is going to be performing.

Dr. Krauss asked Mr. Sachs if there is a body of law that dictates how much of the procedure a PA may do, especially in a circumstance where the surgeon may not be physically in the room. He is concerned this change may be inviting a circumstance for two or three contiguous operating rooms to each have a PA in them with a single supervising surgeon. His next concern is to draw the Members' attention to the Board's prior discussion regarding whether or not a surgeon in an OSS should be required to be board certified and how it may conflict with what the Board is now considering in allowing PAs to do more as a potential primary surgeon. Dr. Krauss just wants the Board to be consistent in the standards that are set for medical care.

Dr. Levine asked for a point of clarification. She believed the language stated "first assistant." Mr. Sachs confirmed that it does read, "first or second assistant." The situation that Dr. Krauss mentioned, could take place. The surgeon could begin a case in the next room while the PA was closing a case.

Dr. Lewis stated that he is uncomfortable with opening this up as it could have negative repercussions. For example, today the Board allows first assistants in certain procedures, but what happens in the future? The Board has seen this issue with some of the recent Senate bills that have been introduced. Dr. Lewis wants assurance for consumer protection.

Mr. Sachs then stated that PAs are dependent practitioners and can only practice in California with supervising physicians and are very proud of the team concept.

Ms. Kirchmeyer offered some additional clarification by reading what the current law reads and then read what the amended language would be.

Dr. Krauss asked if there is a conflict in terminology in saying that one can be an assistant surgeon when the primary surgeon is not in the room.

Dr. GnanaDev responded stating that the primary surgeon has to be in the room during the most crucial part of the procedure. He believes that this new language clarifies the requirements better and is consistent with current medical standards.

Public comment was heard on this agenda item.

Theresa Anderson, Public Policy Director for the California Academy of Physician Assistants, stated that this issue is significant to many of their members and they urge the Board's support for this regulatory change. She asked that it be moved forward to a regulatory hearing where interested parties can provide information to address this issue.

Dr. Bishop clarified that the motion is to ask that the Medical Board consider this regulatory proposal and direct staff to begin the rulemaking process to adopt the proposed language.

Motion carried w/two abstentions (Dr. Krauss and Ms. Wright).

Dr. Levine adjourned the meeting at 5:30 p.m.

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Agenda Item 21 Call to Order / Roll Call

Dr. Levine called the meeting of the Medical Board of California (Board) to order on October 25, 2013 at 9:10 a.m. A quorum was present and due notice was provided to all interested parties.

Members Present:
Sharon Levine, M.D., President
Michael Bishop, M.D.
Dev GnanaDev, M.D.
Howard Krauss, M.D.
Ronald H. Lewis, M.D.
Denise Pines
Gerrie Schipske, R.N.P., J.D.
David Serrano Sewell, J.D., Vice President
Jamie Wright, Esq.
Felix Yip, M.D.
Barbara Yaroslavsky

Members Absent:
Silvia Diego, M.D., Secretary
Phil Tagami

Staff Present:
Veronica Alva, Investigator
Susan Cady, Staff Services Manager II, Central Complaint Unit
Dianne Dobbs, Legal Counsel, Department of Consumer Affairs
Cassandra Hockenson, Public Information Officer
Kimberly Kirchmeyer, Interim Executive Director
Kathleen Nicholls, Supervising Investigator II
Amy Pikschus, Investigator
Dino Pierini, Business Services Officer
Regina Rao, Associate Governmental Program Analyst
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
Natalie Zellmer, Investigator

Members of the Audience:
Theresa Anderson, California Academy of Physician Assistants
Gloria Castro, Senior Assistant Attorney General, Attorney General's Office
Yvonne Choong, California Medical Association
Genevieve Clavreul
Zennie Coughlin, Kaiser Permanente
Julie D'Angelo Fellmeth, Center for Public Interest Law
Long Do, California Medical Association
Jack French, Consumer's Union Safe Patient Project
Karen Ehrlich, L.M., Midwifery Advisory Council
Michael Gomez, Department of Consumer Affairs
Virginia Herold, Board of Pharmacy
Awet Kidane, Department of Consumer Affairs
Christine Lally, Department of Consumer Affairs
Khadijah Lang, M.D., Charles Drew Medical Society
Lisa McGiffert, Consumer's Union
Michele Monserratt-Ramos, Consumer's Union Safe Patient Project
Alison E. Price, L.M.
Deborah Rotenberg, Planned Parenthood Affiliates of California
Bob Sachs, P.A., Physician Assistant Board
Suzan Shinazy, Consumer's Union Safe Patient Project
Carrie Sparrevohn, L.M., Midwifery Advisory Council
Taryn Smith, Senate Office of Research
Mary Helen Ybarra, Health Professions Education Foundation

Agenda Item 22 Public Comments on Items not on the Agenda

Genevieve Clavreul spoke about an issue of patient abandonment by a particular doctor in Pasadena, California.

Ms. Webb asked Ms. Clavreul to not speak in specifics about this case as it may, at some point, come before the Board, but said she could speak in generalities.

Ms. Clavreul asked what could be done about a physician who abandons a patient and falsifies letters about that patient.

Dr. Levine responded by stating that filing a complaint with the Board is the proper way to handle this situation.

Agenda Item 25 Update on Activities of the Board of Pharmacy – Ms. Herold

Ms. Herold announced that there is legislation that will have the Board of Pharmacy (BOP) do inspections of all hospitals in and out of the state or any other pharmacy out of state that ships sterile compounding products into the State of California. This will ensure that for any medication shipped into California the facility will have been inspected by the BOP.

Ms. Herold stated currently some hospitals under an accreditation process are doing sterile compounding without being inspected directly by BOP. Starting in July, that accreditation process has been removed and now requires annual inspections by the BOP if they are doing high risk sterile compounding. The Board has redefined sterile compounding so that it includes injectables, eye administration or inhalation therapy products. They are adding four inspectors to their staff for this particular function.

Ms. Herold stated she is pleased to announce that the BOP and the Medical Board will be collaborating again on two protocols based upon new legislation that was enacted this year. The fact sheet on emergency contraception, which a pharmacist is required to provide when distributing emergency contraception, has been completed. The protocol was approved in February. The fact sheet is being translated into six different languages and is available on the BOP website. Pursuant to Senator Hernandez's bill that provided additional duties for pharmacists to perform, the BOP and the Medical Board have been asked to collaborate on the development of protocols for hormonal contraception therapy and smoking cessation products. The BOP is going to begin this process with a meeting in December, asking Ms. Kirchmeyer to attend so the boards can collaborate on these protocols.

Ms. Herold continued with information on electronic pedigree, which is the process by which each sellable unit of drugs is marked to identify where it has been, and every change in ownership. This is done so that someone cannot buy or sell drugs illegally without there being some observation or risk of being caught. The intent is to safeguard the supply chain. The requirements for manufacturers begin in January 2015, where 50% of the products sold in California have to be serialized and the remaining 50% in January 2016. The pharmaceutical supply chain, which includes manufacturers, wholesalers, pharmacies, and physicians, are not actively involved, but there is federal legislation pending that would pre-empt these requirements. A vote is expected next week.

The BOP has a regulatory hearing at its next Board meeting that will impact when manufacturers ship product directly to the physician for administration. These are typically the more expensive, high risk drugs. The wholesaler actually does the paperwork and ends up owning the product, but never possesses the product. The new regulation will leave out the wholesaler and will provide a very secure method of distribution, thus eliminating many issues that have arisen.

The BOP continues to work on the patient-centered label regulations, which standardizes the requirements on a prescription label, such that the information that patients sees is always in the same format. The label requirements include the name of the patient, name of drug, its strength, instructions on usage, and purpose of the prescription. The BOP committed to

evaluating those label requirements in regulation by December 2013. That process has been completed with just a few modifications to the requirements. The BOP will consider these changes at its next meeting. One of the recommendations is to increase the size of the font. Right now the requirement is 10-point, and the new requirement will be 12-point.

Dr. Levine asked how the electronic pedigree will affect the samples that drug company representatives leave with the physicians' offices.

Ms. Herold stated that as long as they are distributed from the physician's office and not from a pharmacy, it will have no affect at all.

In regards to the BOP's inspections of the hospitals, Dr. GnanaDev asked how these visits were going to take place, i.e. will those visits be planned with CDPH, will they be separate, and will they be unannounced.

Ms. Herold stated the BOP plans to inspect separately and unannounced.

Agenda Item 26 Update/Follow Up from Joint Forum to Promote Appropriate Prescribing and Dispensing – Ms. Kirchmeyer and Ms. Herold.

Ms. Kirchmeyer informed the Members that staff is still planning to have another joint forum with the BOP on prescribing issues. It will take place in middle of 2014 due to pressing issues that are happening with both boards, and will take place in Southern California. Several of the outcomes and needs for educational materials from the prior Joint Forum have been transferred to the Board's Education and Wellness Committee.

The Board has been contacted by an Assistant United States Attorney from the United States Department of Justice (USDOJ) who is working on a summit on prescription drug abuse to be held in January 2014. The USDOJ will be inviting local, state, and federal law enforcement agencies, educators, and several other interested parties to this summit. Board staff, Dr. Levine, and the BOP will be working with the USDOJ on the summit.

Ms. Herold announced that the BOP is doing all-day seminars with the Drug Enforcement Administration (DEA) and giving pharmacists six hours of continuing education to attend. The goal is to have pharmacists become familiar with the different kinds of drug diversion schemes that the DEA enforces. The seminar will discuss prescription drug abuse, the sheer quantity of drugs that are moving through the drug supply, and its impact on public health. The BOP will then discuss corresponding responsibility, which states it is the pharmacist's obligation to review the prescription to be sure that it is not harmful to the patient and it is otherwise legitimate.

Ms. Herold also announced that Saturday, October 26, 2013, is Drug Take Back Day. There is a link on both BOP and the Medical Board website with the details and locations.

Agenda Item 23 REGULATIONS – PUBLIC HEARING

Dr. Sharon Levine opened the public hearing on the proposed regulations to amend Section 1361 of and add Section 1361.5 to Title 16 of the California Code of Regulations, as described in the notice published in the California Regulatory Notice Register and sent by mail to those on the Board's mailing list.

This regulatory proposal would implement, interpret, or make specific sections 315, 315.2, and 315.4 of the Business and Professions Code pertaining to the Uniform Standards for Substance-Abusing Licensees.

Pursuant to these sections the DCA was required to establish Uniform Standards regarding substance-abusing licensees, focusing on the areas of intake and how licensees are monitored after they are placed on probation. This rulemaking will incorporate the Uniform Standards for Substance-Abusing Healing Arts Licensees, as required by law, by proposing to add the standards for a licensee who is placed on probation due, in part, to a substance abuse problem; allowing the Board to impose more restrictive conditions to protect the public. Dr. Levine stated that the date was October 25, 2013; the hearing began at approximately 9:35 a.m.

Dr. Levine informed the Board that written comment was received by several entities. Dr. Levine stated the Members had received those comments for review prior to the meeting. Dr. Levine stated that it is her understanding that staff has recommended amendments to modify the language as presented in the Board materials. She added that after legal counsel provides the staff's recommendations, she would call on those persons who want to testify. The amended language Ms. Webb will be going over was posted on the Board's website on October 11, 2013, with the Board meeting materials. She then asked Ms. Webb to please go through the amendments.

Ms. Webb directed the Members to the Board materials beginning on page BRD 23-22; the first page of the amended proposed regulations. She noted that there are some grammatical changes, but she would be focusing on the substantive changes that are in the language. On page BRD 23-23, subsection (2)(C) currently reads "***be randomly drug tested***" and the recommendation is to change it to "***random biological fluid testing***."

On page BRD 23-24, subsection (2)(F), the following should have been included in the original language, "***No licensee shall be returned to practice until he or she has at least 30 days of negative biological fluid tests***."

On page BRD 23-25, subsection (4)(A), the sentence "***The Board may impose participation in group support meetings***" was deleted.

On page BRD 23-26, subsection (B)(i), "***be randomly drug tested***" and will be changed to "***random biological fluid testing***."

Under subsection (B)(1)(ii), the word "***Drug***" has been replaced with "***Biologic fluid***". Also added to that same section was the sentence "***Prior to vacation or absence, alternative biological fluid testing location(s) must be approved by the Board.***"

In subsection (iii), there is a change to "***biological fluid testing***."

In subsection (iv), there is a change to "***biological fluid testing***" and in the last part of that section an addition of "***Licensee shall be tested on the date of notification as directed by the Board.***"

In subsection (vii), the wording is changed to "***the licensees shall contract with a laboratory or service approved in advance by***", provided that the "***laboratory or service***" meets all the following standards.

On page BRD 23-27, subsection 6, clarification was provided that the entity shall process and analyze the specimen and proved legally defensible test results to the Board within seven (7) "***business***" days of receipt of the specimen. Also added "***The Board will be notified on non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.***"

Under subsection (6)(A), language was added to state "***if any, and workplace monitor, if any***."

On page BRD 23-28, the two changes on that page just clarify the change to "***biological fluid***" testing as well as the final change on page BRD 23-29.

Dr. Levine then called on those persons who wished to testify concerning this proposed regulation.

Julie D'Angelo Fellmeth, Administrative Director of the Center for Public Interest Law (CPIL) at the University of San Diego School of Law, stated she served as the Medical Board Enforcement Monitor from 2003 to 2005 and that CPIL supports this regulation as long as it is significantly amended to be consistent with the Uniform Standards regarding substance-abusing healing arts licensees in the version dated April 2011. She stated she submitted detailed written testimony on October 22, 2013, but would like to provide some background information. She stated that five years ago, in 2008, the Legislature recognized two things. She stated the first was that a substance-abusing health care licensee who is allowed to practice is the most dangerous person out there. Even a moment of impairment can cause irreparable harm to a patient; however, no health care licensing board had established meaningful rules or standards to govern the handling of substance abusing licensees. The Board had a diversion program that diverted substance-abusing licensees away from the disciplinary track and into a monitoring program. That program failed five performance reviews during its 27-year history. The Board unanimously voted to abolish that program in July of 2007. Other boards had diversion programs, the administration of which were outsourced to a private for profit corporation. Some boards do not have diversion programs at all, they attempt to deal with substance-abusing licensees via their enforcement process, which is public. There were no consistent or uniform standards or rules to which participants in these programs or staff of these programs were held.

Ms. Fellmeth stated that Senator Ridley Thomas authored SB 1441, which passed and was signed in 2008, and required the DCA to set up a Substance Abuse Coordination Committee to draft uniform and specific standards in 16 specified areas which "each healing arts board shall use in dealing with substance-abusing licensees whether or not the board chooses to have a formal diversion program." The uniform standards were finalized in April of 2011 and can be viewed on the DCA's website. She added that it is the Board's job to now adopt a regulation that requires the Board to use these regulations in cases involving substance abuse without deviation. In further review, she has found 12 additional omissions or inconsistencies, and have detailed them in her written comments, dated October 22, 2013.

Yvonne Choong, California Medical Association, stated that she had submitted written comments and wanted to give some general comments. She noted that the CMA's comments request clarification. The CMA understands the need for promulgating these regulations, however, there are certain aspects of the proposed amendments that it believes need further clarification in order for a physician to properly comply with, and for the Board to appropriately enforce, those provisions. These items are detailed in the submitted comments. While the CMA recognizes that the Board has been directed by the DCA to promulgate regulations to implement these standards, they want to note that the SB 1441 standards were not adopted pursuant to a standard regulatory process. They are not regulations. The Board is vested with independent authority to promulgate and adopt regulations that serve to strengthen the Medical Practice Act. CMA wanted to remind the Board of its independent authority and responsibility to evaluate these proposed regulatory amendments to ensure it is really appropriate in the context of existing law and practice and in some cases. The CMA applauds the Board's effort to try and look at what the standards require and how they actually fit into what makes sense for physicians.

Michelle Monserrat Ramos, Consumer's Union California Safe Patient Project, stated they support the proposed amendments as long as the full uniform standards are incorporated into the regulations. She stated she felt the need to remind the Board that people have died. She speaks on behalf of the Consumer's Union and advocates on behalf of a specific person. His name was Lloyd Monserrat and he was 36 years old when he died. His surgeon chose crack cocaine over his own personal welfare and the welfare of his patients. The Legislative Counsel, the Office of the Attorney General, and the DCA each issued opinions equivocally stating that the finalized SB 1441 uniform standards are mandatory. They must be used by the healing arts boards in dealing with substance-abusing professionals. However the Board's amended proposed regulations of October 25, 2013, contain omissions. They clearly do not reflect uniform standards as required by law. SB 1441 was explicit that the uniform standards must be adopted regardless of whether or not a board has a diversion program. The fact that the Board does not have a diversion program is not an excuse for failure to adopt any of the uniform standards. The Board should amend the current proposed regulations to include all elements of the uniform standards as required by law.

Ms. Monserrat Ramos added that some of the important elements the uniform standards that have not been included in the current draft regulations include information in uniform standard number four. She stated it failed to specify the requirement of random drug testing for the first year of probation and failed to include requirements of public reporting regarding physicians who tested positive for substance abused and who failed to appear or call in for testing on more than three occasions. She stated the regulations also did not state anything regarding failing to pay testing

costs, or a person who has given an invalid specimen, and 16 other data requirements. In addition, she stated information from uniform standards ten, twelve, thirteen, fourteen, fifteen and sixteen were not included, which required important reporting requirements including an annual report to the Legislature and the DCA.

The legislature sent the Board a letter and a long to-do list of tasks they need to fulfill to show they are meeting their mission and protecting the public. Implementation of the full uniform standards was on that list.

Dr. Levine stated that since there were no further public comments, the hearing was closed. She then stated that due to the number of comments and the timing of when they were received, she recommended that the Board direct staff to prepare a summary of each of the comments and provide a response to the comments for discussion at the next Board meeting. She also recommended that staff be directed to redraft the language and incorporate both the staff's recommended changes and those changes that were meritorious based upon recommendations both in writing and verbally today. Dr. Levine stated that this is a work in progress and edits are going to be necessary. Staff will need time to analyze the comments and provide the Board with recommended edits to the language. The new language will come back before the Board at the next board meeting for review and approval. With the Board's approval at the next meeting, the new language will then be posted for a 15-day comment period. If no new negative comments are received, then the proposed regulation will move forward in the rulemaking process. If negative comments are received, the Board will have an interim meeting next spring to consider the comments and proposed amendments.

Mr. Serrano Sewell made the motion to direct staff to prepare a summary of the proposed comments, a response to those comments, and to amend the language as necessary based upon those comments; s/Ms. Yaroslavsky. Motion carried.

Agenda Item 24 Update from the Department of Consumer Affairs – Ms. Lally

Ms. Lally, Deputy Director of Board and Bureau Relations with the DCA, stated that on behalf of Denise Brown, Director of DCA, she wanted to applaud the Board, Ms. Kirchmeyer, and Board staff for their leadership and partnership to implement the BreEZe project and SB 304. She said that both of these things remind her of a quote that she has in her office that reads, "It's not going to be easy, but it's going to be worth it." She wanted to acknowledge the Board and Board staff's immense investment in both of these projects. She stated she knows that it has been a severe strain on Board staff in preparing for the meeting on SB 304 and they have been nothing but gracious and helpful. Her deepest and sincerest thanks go out to the Board and staff for all of the hard work.

Ms. Lally then welcomed the newest Board Members and stated that in 2013 everyone must complete Sexual Harassment Prevention Training, even if one had taken it last year. Also, the Board Members are required to take the New Board Member Orientation Training (BMOT) and Ethics Training. The BMOT is required to be taken within one year of the assuming office and the Ethics Training is required to be completed with 6 months of the assuming office and then every two years thereafter. The last reminder she wanted to discuss was regarding the Form 700. This form is required to be completed within 30 days after the appointment date and then annually

thereafter. The annual forms are due by April 1st of each year. Lastly, she pointed out that a Form 700 is required when a Member leaves office and is due within 30 days of the departure.

Dr. Levine thanked Ms. Lally for keeping the Board apprised of what is going on at other boards and for supporting the Board Members.

Agenda Item 18 Update on Health Professions Education Foundation – Ms. Yaroslavsky/Dr. Diego

Ms. Yaroslavsky began by introducing Mary Helen Ybarra, a member of the Health Professions Education Foundation (HPEF) Board. Ms. Ybarra serves on several community boards as well as the Corona Fire Safety Committee, the greater Corona Hispanic Chamber of Commerce, the Corona NORCO PTA Community Affairs, and several other organizations. She has also received numerous awards from the Riverside/San Bernardino community. She was recognized as the 71st Assembly District Woman of the Year at the Capitol for extensive volunteer and advocacy work through the district over the past 25 years. She has also received a certificate of Congressional Honor from the Honorable Conglomerate 44th Congressional District.

Ms. Yaroslavsky stated that the HPEF has had a very exciting year. It has had a number of programmatic and fiscal changes, specifically, the application cycle for the 2013/2014 was extended to October 25, 2013, allowing applicants to submit their scholarship and loan repayment information electronically for the first time using a responsive electronic application. The Foundation has an application for a 14 million dollar grant from the California Endowment, which was received and included a provision to award money to 65 allopathic and osteopathic primary care physicians in the year 2013/2104. HPEF was also awarded a one-time award from the Assembly Rules Committee for 2 million dollars. It has the authority to spend another 2 million dollars for the mental health loan assumption program. The HPEF also is making community health workers and medical assistants eligible professions, and has placed them into the allied health scholarship and loan repayment program. The passage of AB 565 has added primary care physician owned and operated medical practices as an eligible practice setting for the Steven Thompson Loan Repayment Program. The passage of SB 21 is the establishment of the UC Riverside Medical School, and, in conjunction with the health facilities of its medical residency program, will assist medical students to be eligible for the Physician Retention Program and also the Steven Thompson Loan Repayment Program.

The investment of the Mental Health Wellness Act of 2013 has been chaptered and will restore the administrative fund percentage from the current 3.5% to 5.0%. The passage of SB 271, the associate degree of nursing scholarship program, has been chaptered, and in exchange for up to 10 thousand dollars in financial aid, the associate degree of nursing students will provide direct patient care in medically underserved communities in the State of California. This bill also eliminated the January 2014 sunset date of this program, so that it will continue indefinitely.

The HPEF has a new Director, Jeanette Taurus, which allows Karen Eisenhower to return to her job as Senior Director of Programming.

Dr. GnanaDev suggested looking at the area of how they can support increasing the number of primary care residencies in California. The biggest issue in primary care in California is the residency programs and when people do their residency in one area, there is a 40-60% chance of them going into practice in that area, especially primary care.

Ms. Yaroslavsky stated she would be happy to talk to anyone that she can about this issue.

Agenda Item 27 Update of Prescribing Task Force – Ms. Yaroslavsky/Dr. Bishop

Ms. Yaroslavsky thanked the staff of both the BOP and the Medical Board for the meeting held on September 23, 2013, to discuss communications between prescribers and dispensers. The meeting was well attended and had representatives from not only prescribing and dispensing communities, but also law enforcement, consumer groups, other regulatory boards and associations, other state agencies, and legislative staff. There were also representatives from the larger chain pharmaceutical companies. There were approximately 80 people that attended this all day meeting. Much of the discussion focused on identifying appropriate patient information to be shared or discussed between the prescriber and the dispenser. A presentation was made by Ms. Sweet on how pain management has evolved and the physician's responsibility in prescribing. DAG Joshua Room provided information on a recent decision adopted as a precedential by the BOP regarding the pharmacist's corresponding responsibility in assuring appropriate prescribing. The attendees formed small groups who engaged in discussion regarding information that could or should be shared. It was encouraging to know that the prescribers and dispensers in the room were not that far apart in regard to the information they felt should be shared. Topics of things they agree should be shared include the diagnosis, information on a patient's treatment plan, validation of information on the prescription, reasons for unusual prescribing, and pain management contracts. Several solutions were identified to assist in eliminating overprescribing, including educating prescribers and dispensers regarding their roles and responsibilities, HIPAA, and red flags; educating consumers about drug diversion and usage; and enhancing the CURES system. The Task Force will be meeting with other regulatory boards to develop a document for prescribers that can provide guidance and information that can be shared and educational tips. The Task Force will be scheduling a meeting between now and the February Board meeting to discuss current pain management guidelines and also focus on best practices for prescribing.

Ms. Yaroslavsky pointed out that the presentation by Ms. Sweet on the evolution of pain management was very well received. The Board received numerous requests for this presentation and it has been placed on the Board's website.

Public Comment was heard on this agenda item.

Genevieve Clavreul stated she is very concerned about what she is hearing. She has submitted information to the Board about Oklahoma's prescription monitoring program that has up to the minute tracking of prescriptions. When trying to put together a new system, she recommends looking at something that already works and clearly CURES is not working as well as it should.

Agenda Item 28 Midwifery Advisory Council – Ms. Sparrevohn

Ms. Sparrevohn, Chair of the Midwifery Advisory Council (MAC), thanked the Board for its support of AB 1308. This bill removed physician supervision from the requirements for a licensed midwife, which will open the door to more workable consulting arrangements between licensed midwives and physicians. This will, in turn, create greater consumer safety and options for women in California. Additionally AB 1308 will allow licensed midwives to legally obtain the medications, supplies, and lab tests needed to safely care for the women they serve in and out of hospitals.

Tosi Marceline was approved by the MAC for the vacant licensed midwife position on the MAC. Ms. Sparrevohn requested the Board's approval for Ms. Marceline's appointment.

Dr. Lewis made a motion to appoint Ms. Marceline to the MAC; s/Dr. Krauss. Motion carried.

Ms. Sparrevohn stated that there is a MAC meeting scheduled for December 5, 2013 and is requesting that, in addition to the on-going regular agenda items, the MAC be able to add an item to appoint a Task Force to discuss development of an informational packet for new Board Members regarding licensed midwives. This packet would be informative and allow new Board Members to understand the issues that licensed midwives face in this State. She would also like the Board to consider allowing the MAC to establish a Task Force to implement AB 1308. The MAC is expecting a report from Ms. Simoes and Ms. Webb at the next meeting on what the particular issues might be from the passage of this bill. The MAC may need a Task Force to address possible changes in the data collection set in an effort to make it similar to nationally collected data points, as required in AB 1308. She also is requesting that staff give a brief report on what the issues are surrounding patient abandonment and how that works for licensed midwives. Lastly, there are some specifics in AB 1308 that will dictate transfers of care.

Ms. Sparrevohn further stated that discussion needs to continue in regards to assistants for licensed midwives. In many areas of the State, it is not possible to have two licensed midwives go to a birth, so assistants are a really important factor in patient safety.

Ms. Ehrlich requested that the Board consider allowing the MAC to go back to four meetings a year as they have gone down to three and she feels there is plenty of work to justify going back to four.

Dr. Levine asked for a motion to allow the MAC to appoint Task Forces and add the discussed additional items to their meeting agenda.

Ms. Yaroslavsky made a motion to allow the MAC to appoint the Task Forces and to discuss the additional agenda items as requested by Ms. Sparrevohn; s/Dr. Yip. Motion carried.

Agenda Item 29 Consideration of Legislation/Regulations – Ms. Simoes

Ms. Simoes reported that she contacted Legislative Offices in the Riverside area as well as Business and Professions Committee staff to invite them to attend the Board meeting, however, they were unable to attend due to their busy schedules.

Ms. Simoes stated that the 2013 Legislative Session ended and the Legislature does not reconvene until January 6, 2014. The Governor has taken action on all bills where the Board took positions. For bills that did not pass the Legislature this year, this is the first year of a two-year session, so those bills have one more year to pass the Legislature.

Ms. Simoes then directed Members to their Legislative Packet and referred them to the Tracker List. The bills in pink were signed into law by the Governor. The one bill in Orange was vetoed by the Governor, and the bills in blue are all two-year bills. Ms. Simoes stated she would be reporting on the bills in pink and orange.

AB 154 (Atkins) allows physician assistants, nurse practitioners, and certified nurse-midwives to perform an abortion by medication or aspiration techniques in the first trimester of pregnancy. The Board will put information on this bill in its *Newsletter* and inform staff of its passage.

AB 512 (Rendon) extends the sunset date in existing law, from 2014 to 2018, for provisions that authorize healthcare practitioners, who are licensed or certified in other states, to provide healthcare services on a voluntary basis to uninsured or underinsured individuals in California at sponsored free health care events. The Board's implementation plan is to notify Board staff of the sunset extension, and ensure the Board will continue to process requests for authorizations from physicians licensed in other states until 2018.

Ms. Yaroslavsky asked Ms. Simoes to request the FSMB put this information in their newsletter as well.

AB 565 (Salas) strengthens the guidelines for selection of applicants to the Steven M. Thompson Physician Corps Loan Repayment Program and expands on the definition of practice settings for this program. The Board will put information on this bill in its *Newsletter*.

AB 635 (Ammiano) allows healthcare providers to prescribe, dispense, and issue standing orders for an opioid antagonist to persons at risk of overdose, or their family member, friend, or other person in a position to assist persons at risk, without making them professionally, civilly or criminally liable. It also extends this same liability protection to individuals assisting in dispensing, distributing, or administering the opioid antagonist during an overdose. The Board will put information on this bill in its *Newsletter* and inform staff of its passage.

AB 1000 (Wieckowski) allows patients to directly access physical therapy services and also allows physicians to employ physical therapists. The Board will put information on this bill in its *Newsletter* and inform staff of its passage.

AB 1288 (Perez, V.) requires the Board to develop a process to give priority review status to the application of an applicant who can demonstrate that he or she intends to practice in a medically-underserved area or population. The Board will develop a process for priority review status, revise the licensing application, and inform postgraduate training programs.

Ms. Yaroslavsky asked why the Board needs to prioritize anyone if licensing is reviewing within its goal. Ms. Simoes stated that this will go into effect should licensing staff fall behind at any point in the future.

AB 1308 (Bonilla) removes the physician supervision requirement for licensed midwives (LMs) and requires LMs to only accept clients that meet the criteria for normal pregnancy and childbirth, and authorizes LMs to directly obtain supplies and devices, obtain and administer drugs and diagnostic tests, order testing, and receive reports that are necessary to the practice of midwifery, among other provisions. The Board's implementation plan is to: notify LMs via letter of the changes to law; notify/train Board staff; update the Board's website with changes to the law; work with interested parties and stakeholders to develop regulations specifying any pre-existing maternal disease or condition likely to affect the pregnancy and any other regulations needed to implement this bill; develop processes and procedures for hospital reporting of each transfer of a planned out-of-hospital birth to the Board and develop a form for this reporting; place on the MAC's agenda a review of the existing reporting data elements and possible changes to coordinate with other reporting systems, including MANA; and provide outreach to new LM applicants that the challenge mechanism will no longer be available effective January 1, 2015.

ACR 40 This resolution proclaims April 9th as DMV Donate Life California Day and April as DMV Donate Life California month, which encourages all Californians to register with the Donate Life California registry when applying for or renewing their driver's license. The Board will put information on this bill in its *Newsletter*.

SB 21 (Roth) requires the UC Riverside School of Medicine to develop a program to identify eligible medical residents and to assist those residents to apply for physician programs, including the Steven M. Thompson Physician Corps Loan Repayment Program. The Board will put information on this bill in its *Newsletter*.

SB 62 (Lieu) was vetoed. This bill was vetoed for fiscal reasons, as it was identified as a State-mandated local program due to the costs to the coroners. This bill will be brought up again as part of the 2014 Legislative Proposals.

SB 304 (Lieu) is the Board's sunset bill, which includes language on a portion of the new issues from the Board's 2012 Sunset Review Report and will extend the Board's sunset date for four years until July 1, 2018. This bill also removes the sunset date from the provisions in existing law related to vertical enforcement. There are some issues that are included in this bill that are not issues raised in the Board's sunset report, including requiring the DCA director to approve the employment of the Board's selection of an Executive Director if hired after January 1, 2014, and amending existing law regarding international medical graduates who have attended a disapproved school to change the practice requirement to 12 years from 20 years. The Board's implementation plan is to: notify and train Board staff; notify interested parties; update the Board's website to reflect all new changes to law that are included in this bill; revise the license renewal form to require email addresses to be reported if a physician has one; develop a process/procedure to send out a confirmation email to all physicians on an annual basis to ensure the Board has the correct email address for each physician; develop a process/procedure to ensure that 801.01 reports are excluded from the requirements in existing law that require an upfront review by a medical expert (these reports can go directly to

investigative staff); and notify the AG's Office to seek ISOs when a licensee fails to comply with an order to compel a physical or mental examination, as this is now grounds for issuance of an ISO.

SB 305 (Lieu), among other provisions, allows all boards under DCA that require licensees to submit fingerprints, including the Board, to request from a local or state agency, certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. This bill specifies that a local or state agency may provide these records and that a board may receive these records. The Board's implementation plan is to notify and train Board enforcement staff.

SB 352 (Pavley) allows physician assistants, nurse practitioners, and certified nurse-midwives to supervise medical assistants. The Board will put information regarding this bill in its N*ewsletter*, update information on the Board's website, and notify Board staff.

SB 493 (Hernandez) expands the scope of practice of a pharmacist to recognize an Advanced Practice Pharmacist, permits pharmacists to furnish certain hormonal contraceptives, nicotine replacement products, and prescription medications for travel, as specified, and authorizes pharmacists to independently initiate and administer certain vaccines, among other provisions. The Board's will notify and train Board staff, and work with BOP and interested parties to develop standardized procedures or protocols for furnishing self-administered hormonal contraceptives and nicotine replacement products.

SB 670 (Steinberg) authorizes the Board to inspect the medical records of a patient who is deceased without the consent of the patient's next of kin or a court order in any case that involves the death of a patient and revises the definition of unprofessional conduct, for a licensee who is under investigation, if the licensee repeatedly fails to attend and participate in an interview of the Board. The Board's implementation plan is to: notify attorneys who represent physicians; notify and train Board staff; revise existing processes and procedures regarding obtaining records for deceased patients; develop a declaration to include with the written request for a deceased patient's records; and revise existing processes and procedures for scheduling physician interviews.

SB 809 (DeSaulnier and Steinberg) establishes the Fund that would be administered by the Department of Justice (DOJ), and would consist of funds ($6 annual flat fee) collected from boards that license prescribers and dispensers, for purposes of funding and upgrading the CURES system. This bill requires DOJ, DCA, and the regulatory boards to identify and implement a streamlined application and approval process to provide access to CURES, requires the Board to periodically develop and disseminate information and educational materials and information on CURES to each licensed physician and General Acute Care Hospital (GACH), and requires prescribers and dispensers, before January 1, 2016, to submit an application to DOJ to obtain approval to access CURES information. The Board's implementation plan is to: post information on the Board's website regarding the fee increase and email physicians; notify and train Board staff; revise the renewal application form to reflect the new fee and revise the renewal letter to reflect the new fee; make necessary changes to the computer system to reflect the fee increase; work with DCA, DOJ and other regulatory boards on a streamlined application process for CURES and provide recommendations on how this application could be integrated as part of the license renewal process; work with DCA, DOJ and other regulatory boards to develop a procedure to enable healthcare

practitioners to delegate their authority to order CURES reports, and to develop an opt-out procedure for those practitioners who do not have a DEA number; provide input to DOJ and DCA on desirable capabilities of the new CURES system for the Board's enforcement program; and work with DOJ and DHCS to identify educational materials related to assessing a patient's risk of abusing or diverting controlled substances and information on CURES and disseminate to each licensed physician and GACH.

SCR 8 (DeSaulnier) proclaims the month of March, each year, as Prescription Drug Abuse Awareness Month and encourages all citizens to participate in prevention programs and activities and to pledge to "Spread the Word….One Pill Can Kill." The Board's implementation plan is to develop and identify outreach materials for dissemination in March 2014.

Public Comment was heard on this agenda item.

Genevieve Clavreul stated that she was unaware of the new CURES system being a brand new system as opposed to an upgrade to the old outdated system. She would like to see the RFP for this. Ms. Kirchmeyer stated that once the RFP becomes an actual contract, it can be found on the Department of General Services (DGS) website.

Ms. Sparrevohn, Chair of the Midwifery Advisory Council, commented that when Ms. Simoes was talking about AB 1308, that some of the Board Members might think that LMs can no longer perform "normal" births. The LMs have never been permitted by law to do abnormal care for women. What is different now is there are some items that are delineated in statute that shows what "normal" would be. The midwifery standard of care for LMs, adopted in 2005, has a fairly extensive list that was developed in conjunction with the American College of Obstetricians and Gynecologists as to those conditions that may affect a pregnancy or delivery.

Agenda Item 29B 2014 Legislative Proposals – Ms. Simoes

Ms. Simoes stated that the Board included new issues in its 2012 Sunset Review Report to the Legislature and in its 2013 Supplemental Report that were not included in SB 304. Board staff has identified the proposals that should be proposed in 2014.

Ms. Simoes stated that in the interest of consumer protection, legislation be written to require that regulations be adopted for physician availability in all clinical settings and for the Board to establish by regulation the knowledge, training and ability a physician must possess in order to supervise other healthcare providers. This item, though in the Board's Sunset Review Report was not included in any legislation in 2013.

Ms. Yaroslavky made a motion to approve this legislative proposal and for staff to seek an author; s/Dr. GnanaDev. Motion carried.

Ms. Simoes stated the Board recommended that a section be added to existing law to require coroners to report all deaths related to prescription drug overdoses to the Board. This language was contained in SB 62 (Lieu), which the Board supported, but was vetoed by the Governor for fiscal reasons. Board staff would like to continue to work with Senate Business, Professions, and

Economic Development Committee on this important consumer protection issue and seek new legislation in 2014.

Dr. Krauss stated that the Board should express its concern by either an affirmation or reaffirmation that the Members wish to explore and exploit all potential avenues of evidence of overprescribing. The public needs to know how important that issue is to the Board and that the Board needs to have some public affirmation of that position.

Public Comment was heard on this agenda item.

Julie D'Angelo Fellmeth stated there was a bill written in 1990, SB 2375 which established the first coroner reporting requirement and that provision was included in the bill at the request of the Coroner's Association as they wanted a mandated reporting requirement, but they also wanted immunity from liability for reporting. She stated that whenever a reporting requirement is established the person requiring the report is also going to want immunity from law suits for making those reports.

Ms. Wright made a motion to have staff continue to work with Senator Lieu on a bill for coroner reporting; s/Dr. Lewis. Motion carried.

Ms. Simoes stated the Board recommended elimination of the 10-year posting requirement in existing law in order to ensure transparency to the public. In the Senate Business, Professions, and Economic Development Committee's background paper, it was recommended that in the interest of transparency and disclosure of information to the public, existing law should be amended to remove the 10-year limit on how long information should be posted on the Board's website. However, SB 304 did not include language that would remove the 10-year limit on posting information.

Public Comment was heard on this agenda item.

Michele Monserratt-Ramos, Consumer's Union Safe Patient Project, stated that they support the proposal. They ask that information be retroactive and all information be posted.

Karen Ehrlich stated that a few times in the last year she has gone on the Board's website to view documents regarding public cases that were previously easily linked on the website and it would direct her to public records. It seems that option is no longer available.

Ms. Kirchmeyer responded by telling Ms. Ehrlich that this is part of the new BreEZe system and that if she would scroll down to the bottom of the page and go across the tabs at the bottom it will list public record actions. Ms. Kirchmeyer offered to walk Ms. Ehrlich through that process after the meeting.

Dr. Lewis made a motion to move forward with legislation to eliminate the 10-year posting requirement; s/Dr. Bishop. Motion carried.

Ms. Simoes stated the Board recommended amending existing law to require a respondent to provide the full expert reviewer report and to clarify the timeframes in existing law for providing the

reports, such as 90 days from the filing of an accusation. SB 304 did include language that would have required the complete expert reviewer report to be provided 90 calendar days prior to the commencement of the hearing. However, after many meetings with the CMA and the Legislature on amendments to address CMA's concerns, the language was pulled from SB 304.

Ms. Yaroslavky made a motion to move forward with legislation to require the full expert reviewer report be provided and to clarify the timeframes for providing the report; s/Dr. Krauss. Motion carried.

Ms. Simoes stated the Board recommended that existing law be amended to include the American Osteopathic Association-Healthcare Facilities Accreditation Program as an approved accreditation agency for hospitals offering accredited postgraduate training programs. This item, though in the Board's Sunset Review Report was not included in any legislation in 2013. Ms. Simoes stated this is a potential omnibus candidate.

Dr. GnanaDev made a motion to move forward with legislation to add this organization to the law; s/Ms. Yaroslavsky. Motion carried.

Ms. Simoes stated that she had two legislative proposals pertaining to the Outpatient Surgery Setting Program. She stated that per existing law, Health and Safety Code Section 1216, clinics licensed by the California Department of Public Health (CDPH), including surgical clinics, are required to report aggregate data to the Office of Statewide Health Planning and Development (OSHPD). This data includes number of patients served and descriptive background, number of patient visits by type of service, patient charges, and any additional information required by CDPH and OSHPD. Before *Capen v. Shewry*, this data was being collected for the majority of outpatient settings, as they were licensed as surgical clinics. However, when physician-owned OSSs fell solely under the jurisdiction of the Board, this reporting was no longer required, which resulted in a serious deficiency of outpatient settings data. Board staff is suggesting that the data collection requirements be put into place for accredited outpatient settings; the data required for reporting would be very similar to the data that surgical clinics are required to report to OSHPD. The Board would work closely with OSHPD on this proposal.

Public Comment was heard on this agenda item.

Lisa McGiffert, Consumer's Union Safe Patient Project stated that they supports this proposal and also urged the Board to consider adding the other areas of reporting they suggested in their written testimony.

Dr. GnanaDev made a motion to move forward with legislation to require the reporting required from licensed clinics also be required of accredited OSSs; s/Dr. Krauss. Motion carried.

Ms. Simoes stated the other proposal related to Business and Professions Code Section 2240 (a), which requires a physician who performs a <u>scheduled</u> medical procedure outside of a general acute care hospital, that results in a death, to report the occurrence to the Board within 15 days. The Board would like to ensure all deaths in outpatient settings are reported to the Board, not just those

that result from a scheduled medical procedure. Board staff suggests striking "scheduled" from existing law. This is a potential omnibus candidate.

Dr. Krauss made a motion to move forward with legislation to strike the word "scheduled" from existing law; s/Dr. GnanaDev. Motion carried.

Agenda Item 9B Consideration of 2014 Board Meeting Dates

Dr. Levine returned to Agenda Item 9B and stated that there is a concern about the February 2014 Board meeting dates being the Thursday and Friday before a holiday weekend. Members discussed moving the February meeting to February 6th and 7th instead of the 13th and 14th.

Ms. Wright made a motion to move the date to February 6-7, 2014; s/Dr. GnanaDev. Motion carried.

Agenda Item 30 Agenda Items for February, 2014 Board Meeting in San Francisco Area

Dr. Levine asked for agenda items for the February 2014 Board meeting. The following items were asked to be placed on the next agenda:

- Presentation from the Department Health Care Services regarding fraud.
- Presentation by Linda Schneider from the AG's Office regarding the Registered Dispensing Optician Program and the lawsuits that are now completed.
- Presentation from Cathryn Nation regarding graduate medical education and the status of funding residency slots.
- An update on Covered California.

Lisa McGiffert, Consumer's Union Safe Patient Project requested a discussion about notifying patients' when a physician is on probation and a discussion on the teleconferencing option for Board meetings.

Dr. GnanaDev announced that in regard to the Executive Director search, the subcommittee was unable to conduct interviews prior to this meeting. The goal is to have the subcommittee interview five to six candidates and then call an interim board meeting in late November or December to pick an Executive Director.

Agenda Item 31 Adjournment

Ms. Yaroslavsky made a motion to adjourn the meeting; s/Dr. Lewis. Motion carried.

Dr. Levine adjourned the meeting at 11:45 am.

_____	_____
Sharon Levine, M.D., President	Date
_____	_____
Silvia Diego, M.D., Secretary	Date
_____	_____
Kimberly Kirchmeyer, Interim Executive Director	Date

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

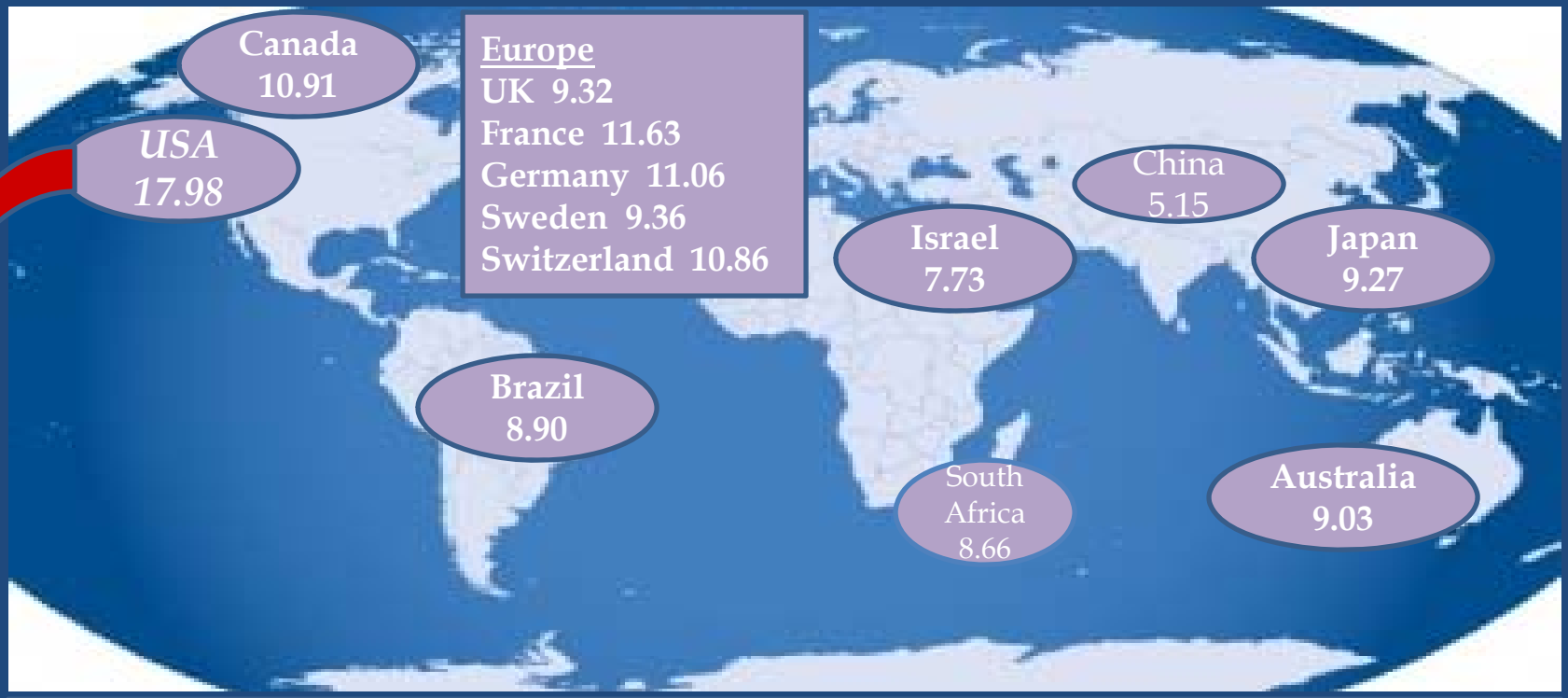
HEALTH CARE FRAUD & ABUSE

PREVENTIVE STRATEGIES IN PROGRAM INTEGRITY

Department of Health Care Services

Audits & Investigations
Medical Review Branch

Healthcare Expenditures Industrialized Nations : % 2011 GDP



World Health Organization
Total expenditure on health as a % of Gross Domestic Product, 2011

Fraud, Waste & Abuse
19%
Thomson Reuters, 2009

US GDP 2011 : $14 .9 trillion
Health care spending: $2.8 trillion

Issues and Examples

Mistakes | **Inefficiencies** | **Bending the Rules** | **Intentional Deception**

Error

Incorrect Coding

Waste

Medically Unnecessary Service

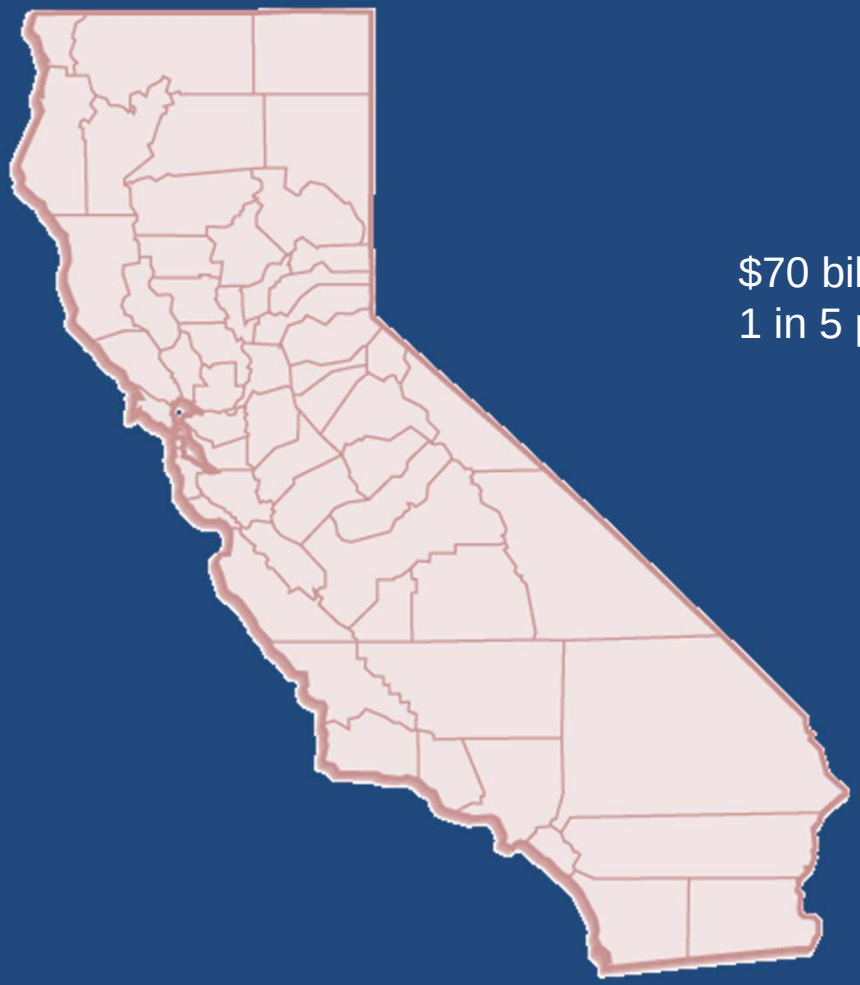
Abuse

Improper billing practice

Fraud

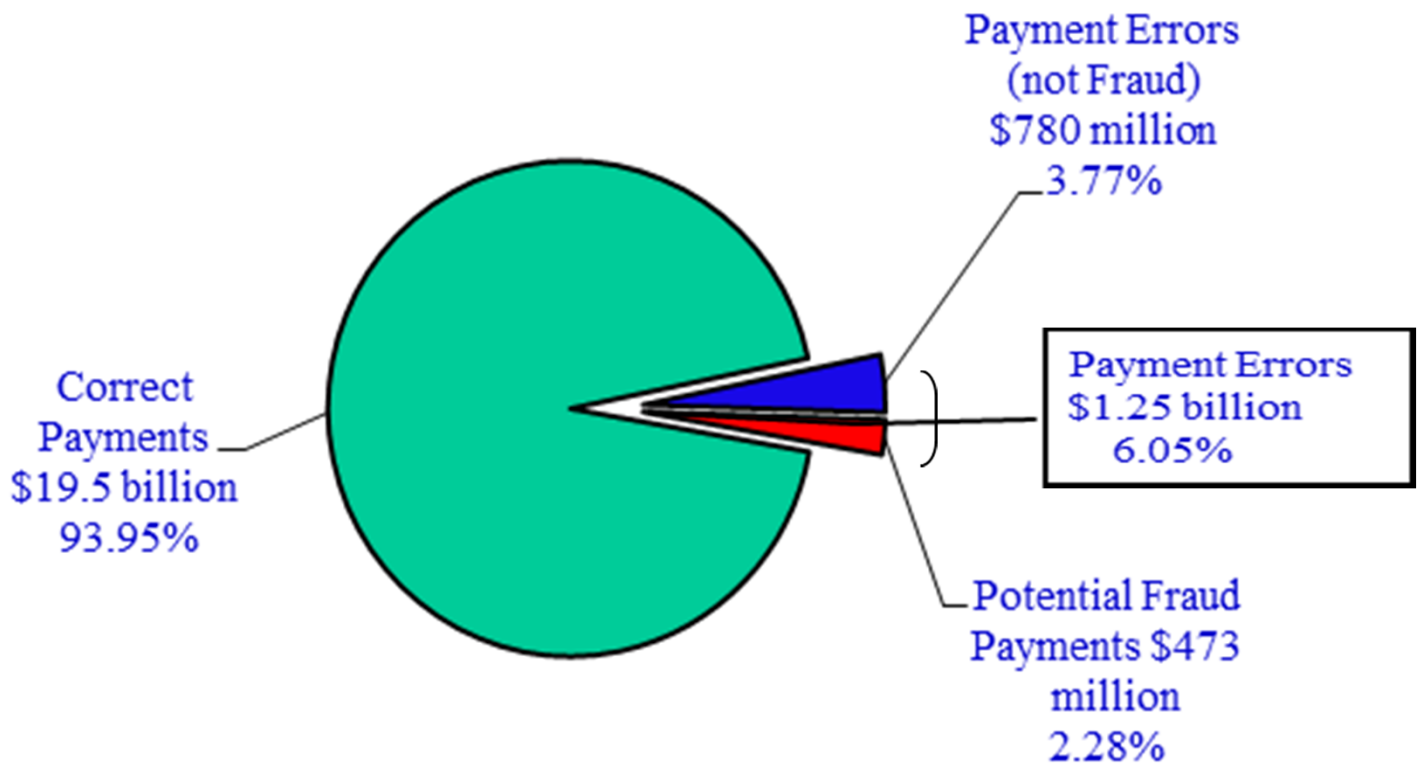
Billing for unnecessary Services or Supplies not Provided

California Department of Health Care Services



$70 billion (2014)
1 in 5 people covered

Medi-Cal Fee-for Service Payment Proportions Paid Correctly Error, Including Fraud - 2011



Fraud = Bad Practice

COLOR CODE LABELS
500 LABELS
Alphabetic
FOR USE WITH END TAB PRO
SELF-ADHESIVE

Con Artists

- A con artist is a professional
- A con artist needs a conduit
- A con artist needs a victim to take the fall
- A con artist doesn’t care about the harm

Physicians

- Focus on medicine
- Not taught about business
  - (e.g. Don’t sign a blank contract!!!)
- The National Provider Identifier is like a credit card without a limit

Program Integrity

- Deficit Reduction Act of 2005
- Program integrity is the practical concept that programs should be organizationally and structurally sound
- Health care – programs efficient, effective, ethical
  - Corollary: prevent fraud, waste & abuse

Medical Review Branch

- Medical and Audit staff
  - Pre-Enrollment Reviews
  - Utilization Controls
  - Sanctions
  - Referrals
  - Studies
  - Compliance Audits
  - Outreach

Referrals

- Medical Board
- Pharmacy Board
- Centers for Medicare and Medicaid
- Department of Justice

Eliminate "Pay & Chase"

- Prevention
  - Disclosure
  - Knowledge is Power
  - Stop unlicensed practice
- Affordable, quality care
- Best use of dollars

Screen Applicants

Physician Office

Current FDA Approved Drugs

Issues in Provider Community

- Identity Theft versus Identity Lease
- Avoid Patient Harm
- Close the Knowledge Gap

Outreach Efforts

- Professional Societies
- California Medical Association Webinars
- Partner with Centers for Medicare & Medicaid
- Residency Programs
- Journal articles
- Education materials
  - Patients
  - Providers

Next Steps

Need to Reach a Wider Audience

Online Training

- 3 one hour Interactive Webinars
- Developed with Xerox (fiscal intermediary)
- Free
- Goal – Free Continuing Medical Education
- Subject Matter Experts

Subject Matter

- Module I
  - Impact of fraud, waste & abuse
- Module II
  - Prescribing & Referring
- Module III
  - Documentation & Internal Controls

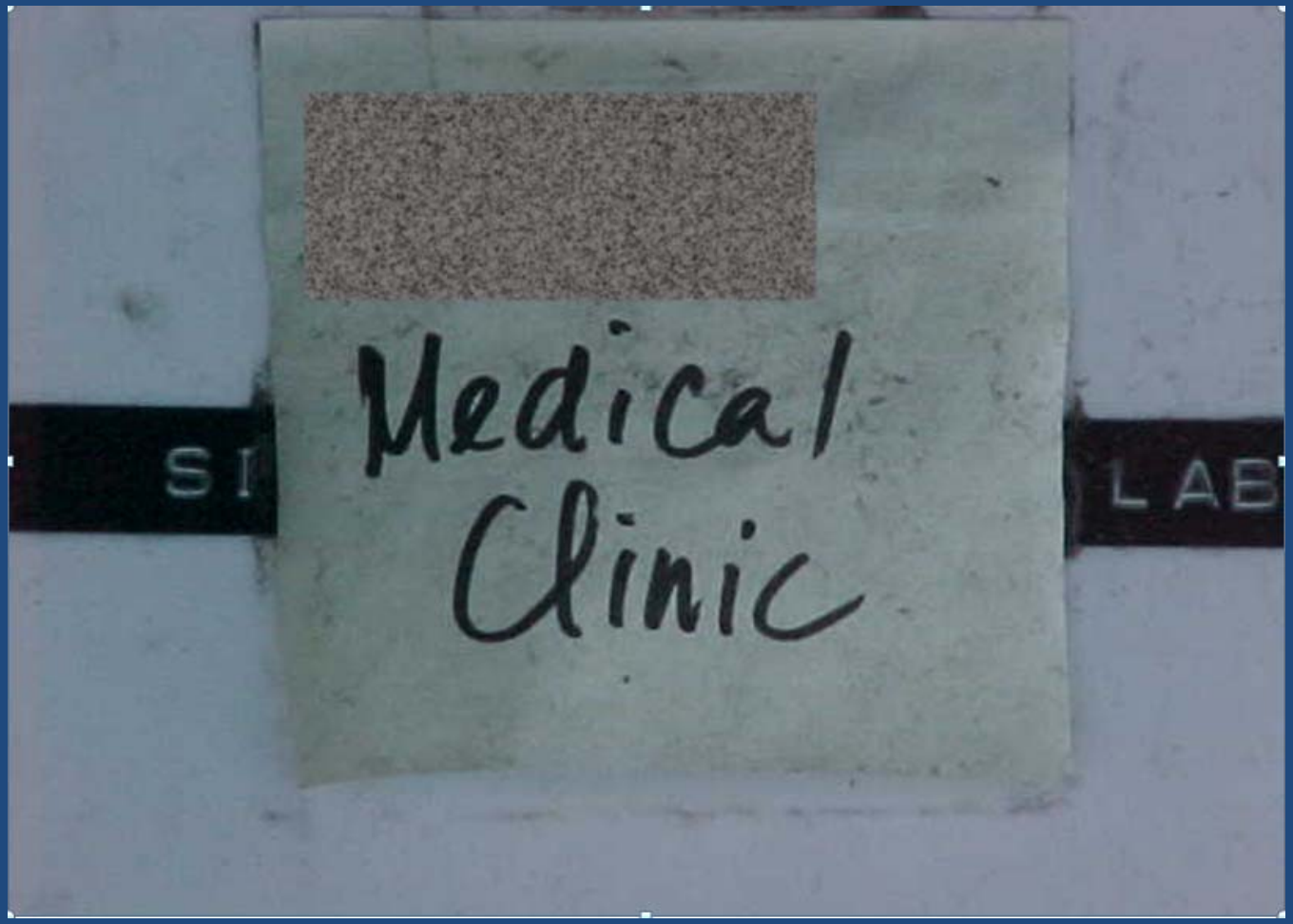
Module II

- Timeliness
- Impact of prescribing
- Videos/input from other experts
- Welcome Medical Board support

Change the Dynamic

- Attitudes
- Education
- Benefit for the greater good

An Ounce of Prevention



Protect Your practice

- Do not sign something unless you have read it, understand it, and have retained a copy.
- Document your services thoroughly and legibly, including the medical reasons behind the services provided.
- Know your employees, especially the qualifications of those providing billing services.
- Beware of individuals offering to pay you to be clinic "medical directors" with little or no patient contact.
- Do not allow patients or their families to pressure you into ordering medically unnecessary services or products.

Suspicious Behaviors

Patients reporting receiving unrequested goods or services. (Delivery of unsolicited goods or services to patients is a problem. We want the patient to report to a physician if unsolicited goods or services are received.)

Offers of money or goods in exchange for allowing unnecessary services or testing.

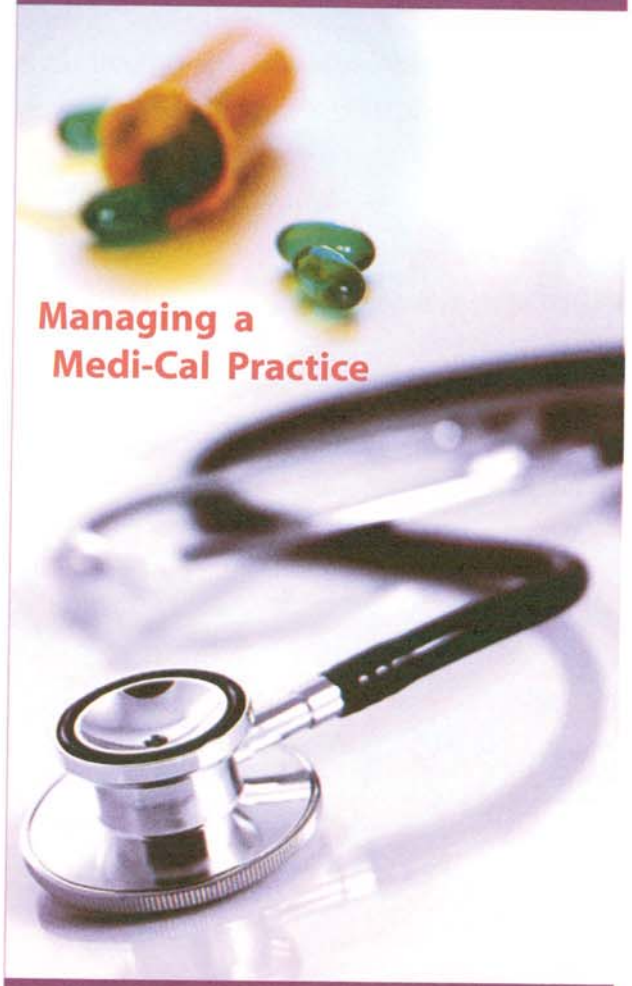
Patient frequently requesting script for replacing "lost" prescriptions, particularly narcotic or high cost medications.

Report Fraud and Abuse

- DHCS Medi-Cal Fraud Hotline:
  - Toll Free 1-800-822-6222
  - Caller may remain anonymous
  - Languages available are English, Spanish, Russian, Vietnamese and Cambodian
- DHCS Fraud Prevention email: stopmedicalfraud@dhcs.ca.gov
- Written complaint to:
  Department of Health Care Services
  P.O. Box 997413
  Sacramento, CA 95899-7413
- Attorney General Medi-Cal Fraud and Elder Abuse Hotline:
  - Toll-free 1-800-722-0432

California Department of Health Care Services
Audits and Investigations Division

California Department of Health Care Services (DHCS)



Managing a Medi-Cal Practice

PROTECT MEDI-CAL AGAINST FRAUD, WASTE AND ABUSE

Knowledge is the best defense.

The Department of Health Care Services (DHCS) seeks to promptly pay providers and eliminate fraud, waste and abuse. Most claims are paid with the assumption that the claims are accurate and most services are approved under the belief that the services were medically necessary and delivered as represented.

This system best serves beneficiaries and providers. However, it does provide an opportunity for erroneous payments.

What Is Fraud?

Fraud is the intentional deception or misrepresentation perpetrated to acquire an excessive Medi-Cal reimbursement or other unauthorized benefit.

Although 95 percent of Medi-Cal billing is accurate, the small minority of fraudulent providers account for $1 billion in annual loss to California taxpayers.

Why Be Concerned?

Fraud, waste and abuse drain health care dollars and resources from everyone. Fraud, waste and abuse can result in incorrect information in your patient's health record.

We share a responsibility to prevent fraud. A vigilant provider is a strong defense against fraud, waste and abuse.

Conversely, inattention to detail could jeopardize your practice or otherwise limit your ability to participate in Medi-Cal and Medicare programs.

Fraud May Present As:

- *charges for goods or services that were not provided or were not necessary*
- *kickback arrangements for referrals for services, drugs or supplies*
- *use of the wrong medical identity*

Waste and abuse also represent a significant portion of payment errors. These can occur when:

- *providers order excessive services or drugs and supplies*
- *patients request and are granted services that are not utilized or have questionable medical value*
- *higher cost services or products are ordered when there are equivalent lower cost options*
- *providers are unfamiliar with the rules governing care under the Medi-Cal Program*

PRO Pubs 08/11

Reporting

What to Report

Report if your medical identification number has been lost, stolen or otherwise compromised.

Report suspicious activities, such as waiving of copayments or rewarding with gifts or bonuses.

Report suspicious individuals or companies, such as those conducting door-to-door or telephone marketing.

Where to Report

Three Options for Reporting Medi-Cal Fraud

1. DHCS Toll-Free Medi-Cal Fraud Hotline: 1-800-822-6222
   - Caller may remain anonymous
   - Languages available are English, Spanish, Russian, Vietnamese, and Cambodian
2. DHCS email: stopmedicalfraud@dhcs.ca.gov
3. Attorney General Medi-Cal Fraud and Elder Abuse Toll-Free Hotline: 1-800-722-0432
   - $1,000 reward offered for information leading to the arrest and conviction of providers of Medi-Cal goods or services who commit fraud

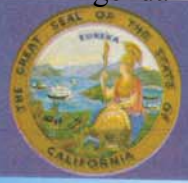
How to Report

Collect the following facts about the situation:

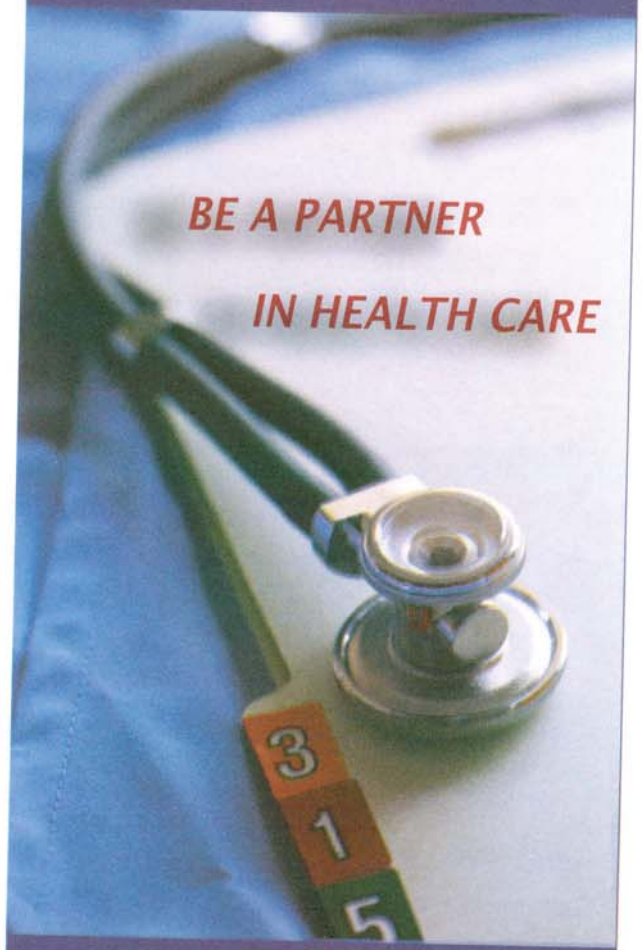
- Service, product or action you are questioning
- Reasons for concern
- Provider's name and identifying number
- Date of occurrence
- Dollar amount
- Your name and medical identification number

WORKING TOGETHER

When patients, health care providers, and Medi-Cal work together against health care fraud, the benefit is felt throughout the entire system. Thank you for your help.



California Department of Health Care Services (DHCS)



PROTECT MEDI-CAL AGAINST FRAUD, WASTE AND ABUSE

How You Can Help

- *Protect your medical benefits identification number*
- *Be alert for possible schemes and scams*
- *Report concerns*

What Is Health Care Fraud?

Health care fraud is an intentional attempt by someone to receive unearned money or undeserved benefits from an insurance program.

It can take the form of…

- *charges for goods or services that were not provided or were unnecessary*
- *kickback arrangements for referrals*
- *use of the wrong medical identity to acquire goods or services for someone else*

Why Be Concerned?

Fraud, waste and abuse drain health care dollars and resources from everyone.

- *This hurts you, your fellow patients and your health care providers.*

Fraud can result in incorrect information in your health record.

- *This can mislead your doctor and result in improper treatment.*

Fraud can complicate your life.

- *It can bring legal authorities to your door.*

Identifying Possible Schemes and Scams

Be suspicious of the following:

- *Offers of free services or gifts in exchange for your medical identification number.*
- *Visits by solicitors, calls by telemarketers or requests for payment over the telephone or Internet.*
- *Pressure tactics for you to request or accept medical services or supplies that you do not need.*
- *Charges for services or supplies you did not receive.*
- *Copayments automatically being waived (kickbacks).*

Protecting Your Medical Benefits Identity

Keep your personal information (i.e., Social Security Number, medical identification number, and credit card numbers) safe and secure.

Do not allow your medical identity to be borrowed and used by another person.

Do not give your personal information to solicitors or marketers. Only give your personal information directly to your doctor or other official health care providers.

PRO Pubs 08/11

Expanding Physician Education in Health Care Fraud and Program Integrity

Shantanu Agrawal, MD, MPhil, Bruce Tarzy, MD, Lauren Hunt, MPH, Julie Taitsman, MD, JD, and Peter Budetti, MD, JD

Abstract

Program integrity (PI) spans the entire spectrum of improper payments from fraud to abuse, errors, and waste in the health care system. Few physicians will perpetrate fraud or abuse during their careers, but nearly all will contribute to the remaining spectrum of improper payments, making preventive education in this area vital. Despite the enormous impact that PI issues have on government-sponsored and private insurance programs, physicians receive little formal education in this area. Physicians' lack of awareness of PI issues not only makes them more likely to submit inappropriate claims, generate orders that other providers and suppliers will use to submit inappropriate claims, and document improperly in the medical record but also more likely to become victims of fraud schemes themselves.

In this article, the authors provide an overview of the current state of PI issues in general, and fraud in particular, as well as a description of the state of formal education for practicing physicians, residents, and fellows. Building on the lessons from pilot programs conducted by the Centers for Medicare and Medicaid Services and partner organizations, the authors then propose a model PI education curriculum to be implemented nationwide for physicians at all levels. They recommend that various stakeholder organizations take part in the development and implementation process to ensure that all perspectives are included. Educating physicians is an essential step in establishing a broader culture of compliance and improved integrity in the health care system, extending beyond Medicare and Medicaid.

Editor's Note: A commentary by M.A. Lyles appears on page 1061.

Health care fraud is a pervasive element of the current delivery system for both public and private payers in the United States, and schemes like those described below are perpetrated every day.

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Dr. Tarzy is lead medical consultant, Medical Review Branch, California Department of Health Care Services, Sacramento, California.

Ms. Hunt is health insurance specialist, Center for Program Integrity, Centers for Medicare & Medicaid Services, Baltimore, Maryland.

Dr. Taitsman is chief medical officer, Office of the Inspector General, Department of Health and Human Services, Washington, DC.

Dr. Budetti is deputy administrator for program integrity and director, Center for Program Integrity, Centers for Medicare & Medicaid Services, Washington, DC.

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Acad Med. 2013;88:1081–1087.
First published online June 26, 2013
doi: 10.1097/ACM.0b013e318299f5cf

Scope of Program Integrity Issues

Beginning in 2002 and continuing until they were arrested in 2010, owners of a mental health services company executed a Medicare fraud scheme. They submitted fraudulent claims in seven different locations throughout south Florida and Orlando and paid kickbacks to owners and operators of assisted living facilities and halfway houses in exchange for delivering patients to sham treatment programs. In total, Medicare paid over $200 million in unnecessary or illegitimate services, and, to date, 11 individuals have pleaded guilty or been convicted at trial.[1]

In southern California, 17 individuals, including a pharmacist and a physician, were charged with stealing millions of dollars from Medicare and Medi-Cal, the state Medicaid agency, in an elaborate prescription drug scheme that allegedly resulted in the government repeatedly paying for the same pills. Using stolen Medicare beneficiary cards, members of the ring were alleged to have obtained prescriptions for expensive drugs from the complicit physician, filled the prescriptions at pharmacies using the stolen Medicare cards, and funneled the drugs back to other pharmacies involved in the scheme.[2]

Fraud, such as these schemes, not only drives up health care costs but also reduces the funds available for legitimate health care services and endangers the long-term solvency of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Currently, nearly 100 million Americans depend on these public, tax-funded programs for health care.[3] Fraud can take many shapes, but common schemes involve billing for services or supplies that were never rendered or were clearly medically unnecessary. Violations also can include *up-coding*, or billing for a more expensive service or procedure than the one performed, or double billing for the same service or product. In one example of a physician-initiated scheme, an Illinois psychiatrist was found to have billed Medicaid for so many clinical hours of activity in one year that those hours nearly exceeded 24 hours each day.[4] Other providers have been found to bill services for patients who were dead at the time the alleged services were performed.

Despite these examples, the vast majority of physicians, suppliers, and other providers are honest and do not seek to defraud or abuse public or private programs. Hundreds of thousands of clinicians help to serve Medicare and Medicaid beneficiaries daily by providing necessary, high-quality care. Physicians, however, may generate other forms of improper payments, which

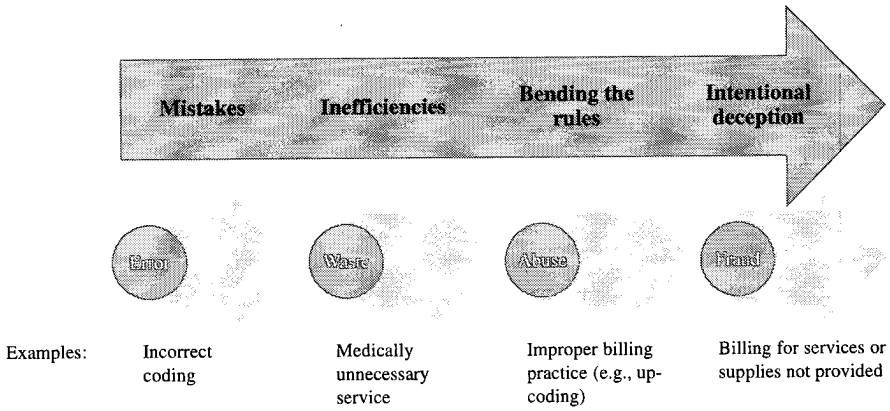

Figure 1 Spectrum of program integrity issues and examples of each.

can create challenges for the integrity of public and private programs.[5] *Program integrity* (PI) spans the entire spectrum of improper payments, from fraud to abuse, errors, and waste in the health care system (see Figure 1). Relatively few physicians will perpetrate fraud or abuse, but nearly all physicians will contribute to the remaining spectrum of improper payments.[6] In addition, unsuspecting physicians may become involved in fraudulent activities through their associations with intentional fraud perpetrators.

Like other complex systems with numerous financial transactions, Medicare, Medicaid, and CHIP are susceptible to payment errors called improper payments. These can result from a variety of circumstances, including billing for services with insufficient or lack of documentation, incorrectly coding claims, or providing services that were not "reasonable and necessary." Many identified improper payments by physicians and suppliers relate to claims for which the information in the patient's medical record did not support the services billed.[7] Previous articles have characterized other forms of physician-driven waste, including failures of care delivery, lack of coordination, and spending on services that do not improve or preserve health. In 2012, the Institute of Medicine estimated that the U.S. health care system loses about $765 billion a year to waste. Of that $765 billion, about $210 billion is attributable to unnecessary services, $190 billion to excess administrative costs, $130 billion to inefficiently delivered services, $105 billion to excessive prices, $75 billion to fraud, and $55 billion to missed prevention opportunities.[8]

Physicians generate improper payments not only from the services they perform and bill directly but also from the services and supplies that they either order or for which they make referrals, such as durable medical equipment, diagnostics, laboratory analyses, and prescription drugs. The expenditures for such physician-authorized services and supplies far outstrip physician professional fees. One prominent example is improper payments for diabetic supplies, which are too often provided in excessive quantities or to beneficiaries who do not need them. These improper payments are caused in part by the lack of appropriate physician documentation accompanying orders. Payment errors for glucose measuring supplies, for example, amounted to more than $1 billion in waste in 2010 for Medicare alone.[9]

Improper payments of any type cause significant financial impact. For consumers, improper payments can mean higher premiums and out-of-pocket expenses, as well as potentially reduced benefits. For employers, improper payments increase both the cost of providing insurance benefits and the overall cost of doing business. Beneficiaries also can potentially be harmed through the compromising of their medical records, such as by receiving services that are not appropriate for their actual health issues.[10]

Organized medicine has long recognized the need to codify medical services so that physicians are appropriately paid relative to their peers. The American Medical Association's Current Procedural Terminology (CPT) guidelines represent national provider–payer alignment on the importance of "uniform language that accurately describes the medical, surgical, and diagnostic services … and provide[s] an effective means for reliable nationwide communication among physicians, patients, and third parties."[11]

The importance of consistent, service-appropriate documentation is relevant not only to the payer community. The relationship between documentation and coding is woven into the fabric of the health care system. The 2012 CPT report states that it is useful for "the development of guidelines for medical care review" and is "applicable to medical education and outcomes … and quality research by providing local, regional, and national utilization standards."[11] Thus, although the nexus between care and documentation may seem at times strained on an individual physician basis, its overall significance is broadly appreciated by the various health care stakeholders.

Physicians can be critical safeguards against such improper payments. The Centers for Medicare and Medicaid Services (CMS) employs a broad strategy to address fraud, abuse, and other improper payments, but the success of these approaches depends on increased awareness in the physician community. Health care fraud prevention education, then, is vital to mitigating the financial and health consequences of improper payments of all kinds.

Although the scope of PI has often been couched in terms of wasteful or abusive services, the overall goal is to ensure that the highest level of appropriate and medically necessary health services possible for the available dollars is provided. PI issues must play a role during discussions about best practices and standard protocols. Although certain care practices will recommend unnecessary care to some individuals, overall such methods should provide improved outcomes and/or lower costs to the greater population. Debates over the appropriateness and timing of health screening tests or protocol-driven care, for example, often reflect the tension between cost/benefit and patient concerns.

We, however, also must acknowledge that we are treating patients, both individually and as population groups. Issues of public safety, quality of care, and human

dignity must be a part of PI discussions and, at times, take priority. Although PI may be a relevant consideration in care discussions, it may not always be the most appropriate lens through which to view a problem like patient safety or poor quality care. In these discussions, the overriding concern should be something more than cost. All of these factors must be part of ongoing discussions regarding health care policy and approaches to adequate PI, and these discussions should rightfully involve physicians, payers, governmental oversight agencies, and public stakeholders.

Current Physician Education in PI

Despite the significant impact that fraud and other PI issues have on public and private insurance programs, efforts to control these issues historically have focused on the enforcement of policies and the recovery of funds. More recently, however, especially with the passage of new PI authorities in the Affordable Care Act in 2010, such initiatives have begun to focus on prevention. Still, medical education does not include sufficient emphasis on fraud awareness or best practices for ensuring proper payments. Some corporate integrity agreements (CIAs) from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) may include PI training, but it is not a general requirement in all CIAs or for all providers.

Current education programs and challenges to addressing PI issues

A survey by the HHS OIG revealed a lack of consistent efforts at medical schools and residency programs to teach trainees about fraud and abuse. Only one-third of the schools contacted provided "some" training on these topics.[12] In small-group discussions with residents, the California Department of Health Care Services (DHCS) found little practical awareness of PI issues such as identity theft, fraud schemes, and documentation requirements.[13] In addition, a study done at the University of California, Irvine, revealed that foreign medical graduates represented a significant percentage of the physicians sanctioned for Medicaid billing violations.[4] Educational efforts, then, to be broadly effective, need to target all physicians and areas of known vulnerability.

Few services in government-sponsored health care programs require preauthorization, and payments to physicians are made under the assumption that claims are accurate. Yet studies have shown that the information gap between claims and documentation is significant. For example, a recent OIG report revealed that 64% of claims for surgical debridement cases did not meet Medicare program requirements, resulting in $64 million in overpayments.[14] In addition, in 2009, DHCS released its Medi-Cal Payment Error Study which showed that claims errors cost the state over $1 billion per year.[15] The CMS Comprehensive Error Rate Testing (CERT) process identified an overall error rate of 8.6% of payments within the Medicare fee-for-service program in 2011, amounting to nearly $30 billion.[16] The CERT process also identified insufficient documentation, lack of medical necessity, and coding errors as the main contributors to the overall improper payment rate. The 2010 Implementation of Recovery Auditing at the Centers for Medicare and Medicaid Services report also identified a variety of reasons for overpayments for Medicare services, including payment for services and items that did not meet coverage and medical necessity criteria, were not correctly coded, or for which the accompanying documentation submitted did not support the ordered service.[17]

Physician education often does not address the rules governing the relationship between documentation and claims—specifically, the requirements of public programs. This lack of guidance certainly contributes to the measured error and overpayment rates. In addition, the increasing numbers of midlevel professionals (e.g., nurse practitioners and physician assistants) providing health care services add complexity to preventing PI issues. Supervising physicians are responsible for ensuring that these individuals have the required oversight, practice within the scope of services for which they are trained, are appropriately licensed and credentialed, and are identified as the rendering practitioner. Even with strict protocols, the opportunities for billing errors are magnified. Physicians, then, need additional education not only in preventing PI issues themselves but also in supervising midlevel professionals who may be unaware of such issues.

Health care innovation presents another set of challenges to preventing PI issues. For example, while offering numerous benefits for improved quality and coordination of care as well as assisting with long-standing documentation challenges such as legibility, electronic medical records (EMRs) also create vulnerabilities. The use of repetitive language stemming from electronic templates and cloning could create documentation that misrepresents the true nature of the patient–physician encounter. The ability to "populate" data fields in the elements of a history and physical with one click can compromise the role of a physician in affirming each individual answer. This practice can lead to inaccuracies embedded in the patient record and responses that are inappropriate. In addition, some EMR programs contain prompts that encourage physicians to document additional and potentially unnecessary elements of a history or physical to "code" for a higher level of service. Thus, to be successful, PI education programs also need to address health care innovations.

Physician-identified concerns and liability issues

Physicians and trainees themselves have identified a need for significantly more PI education. A 2010 survey, for example, found that 82% of emergency medicine residents and 100% of attendings wanted additional PI education, specifically in adequate documentation and billing.[18] The findings from this study corroborated those from a 2009 survey of pediatricians, which found that 81% of respondents favored additional PI training that "highlights the acute and pervasive perception regarding the inadequacy of training in this specific area."[19] This perceived gap in training occurred despite the fact that the American Academy of Pediatrics passed a resolution in 2006 to enhance PI training for residents. The authors of the 2009 report were careful to note that "pediatrics is not the only specialty where training in billing and coding is considered inadequate." Perhaps the most alarming findings, clearly emphasizing how early PI education must be implemented, are from a 2010 survey which found that 14% of interns from three different residency programs reported engaging in "falsification of patient records," including back-dating

notes and documenting physical findings that they personally did not obtain.[20]

Physicians' lack of awareness of PI issues makes them more likely not only to submit inappropriate claims and document inadequately in the medical record but also to become victims of fraud schemes. Such schemes include sophisticated operations by organized crime. Such groups, for example, can gain access to physicians' medical identities through compromised records or by physicians themselves unknowingly disclosing personal information. One such ploy is to offer a physician a position as the "medical director" of a non-physician-staffed clinic. The physician is given some remuneration to sign charts completed by others, ostensibly for oversight. What the physician may fail to realize, though, is that his or her medical identity then is used to bill Medicare, Medicaid, or other insurance programs for unnecessary or undelivered services at the clinic and possibly other locations. In another such ploy, a specialist, such as a radiologist, may be asked to "overread" diagnostic studies for a clinic which bills for the specialist's services. What the specialist may fail to realize is that the services are for patients recruited from vulnerable populations, such as the homeless, and are medically unnecessary. The result of such schemes is that the physician whose identity was misused may lose the ability to participate in public and private insurance programs, thus becoming potentially unemployable.

Even in these examples, the physician is responsible for performing due diligence to ensure that his or her employment positions and billing practices are legitimate and that he or she abides by good medical practice. Physicians who agree to sign charts without evaluating the volume and quality of services delivered or to "overread" films can be culpable. Compensation disproportionate to the work being done should raise a red flag for any medical professional, and he or she should further investigate and report such situations.

PI issues are not confined to the fee-for-service arena. Medicare auditors, for example, are familiar with issues such as diagnostic-related group up-coding or inaccurate increases in the risk adjustment factors which determine payments to Medicare managed care plans.[21] In addition to the direct financial impact, these inaccuracies, whether deliberate or not, corrupt patient medical records. Successful diagnostic coding is dependent on physicians having sufficient training in recognizing the sometimes subtle but important differences embedded in the codes.

Educational requirements and approaches

The complexity of these PI issues poses challenges for education. Multiple authors have suggested that deceptive physician billing practices against third-party payers in general, and public programs in particular, are based in part on the conflict between physicians' need to care for their patients and the rules of the insurers' governing benefits.[22,23] Although this rationale is self-serving, a number of parties believe that physician education should include training in the ethics governing patient care and the consequences of PI shortcomings to the individual, the profession, and the health care system.[4,12,23] Such a program should be designed to increase physicians' awareness of how they could unintentionally become involved in fraudulent activities, the nexus between documentation and coding, patient demand issues, and the consequences of inappropriate behavior.

An advantage of teaching hospitals educating residents and fellows about PI issues is that faculty and other physicians also will learn the information. Long-standing members of the academic medicine community may remember Physicians at Teaching Hospitals (PATH) audits that OIG initiated in the late 1990s. The government collected millions of dollars from numerous teaching hospitals for common billing problems, including up-coding and inadequate supervision or personal participation in procedures billed by attending physicians but performed by trainees.[24] For example, the University of Pennsylvania agreed to repay $10 million for disputed billings and $20 million in damages, and Thomas Jefferson University agreed to repay $6 million for disputed billings and $6 million in damages. Currently, OIG is undertaking a series of hospital compliance audits. Teaching hospitals that better educate their physicians, both trainees and faculty, can better avoid billing improprieties that would ultimately make the hospital vulnerable in government audits and enforcement actions.

Errors, abuse, waste, and fraud have a significant impact on our nation's ability to address the health care needs of its citizens, particularly with regard to government-sponsored programs. The cost of such issues can be measured not only in dollars but also in impact on the overall quality of patient care. Many have acknowledged widely the importance of physician education in this domain. For example, Michael Lubao[25] stated that "payers can make a valuable contribution to the health care community by educating physicians in such a way that they can avoid claims submission mistakes and elevate their billing practices." Julie Taitsman,[12] OIG chief medical officer, wrote, "Better education can provide honest physicians with a road map to keep them from losing their way." The 2010 CMS recovery auditing report included the creation of a robust physician education program as an essential element in the effort to reduce improper Medicare payments.[17] Given the magnitude of PI issues, private and public payers, medical educators, health care organizations, regulators, and specialty societies should consider making PI education mandatory for participation, licensure, or board certification.

Despite the diverse evidence that additional PI education is needed, we also should consider whether such educational programs will impact and improve behavior. A small but growing body of work exists in this area, though additional research is required. Educational interventions have, for example, been shown to improve elements of documentation.[26] They also have been shown to improve billing and coding, particularly for evaluation and management (E&M) services, a primary area of concern for physicians.[27,28] Beyond such research, public payers have used educational interventions as a means of addressing aberrant or outlier billing and practice behavior. The Individual Provider Claims Analysis Report[29] is a tool that DHCS used to raise awareness among physicians and other providers about billing and prescribing behavior through peer comparisons. The program has yielded significant changes in E&M billing as well as pediatric drug prescription

practices, the tool's initial focus areas. CMS also has been successful in lowering the improper payment rate in several areas, in part because of proactive education efforts. Internal data from CMS, for example, revealed increased provider documentation compliance after webinar-based educational programs. Together, these results lead us to believe that PI education, like education in a multitude of other areas in health care, such as clinical quality and patient safety, can improve practice.

Together, these education efforts and the published literature identify features common to successful PI education programs. First, they emphasize the need for focused and dedicated time for education through a variety of mechanisms. Second, they highlight that education should start early in graduate medical education, potentially even in medical school. Third, they underscore that education must be repeated periodically to enforce positive behaviors and dispel negative behaviors which may progress from improper practices to those that are abusive and beyond. Anecdotal experience suggests that a team-based approach to learning is best, with providers, compliance staff, and others working together to improve PI practices. Finally, they stress that peer comparisons can aid physicians in understanding their behavior and can create an impetus for change.

Proposal for a Model PI Education Curriculum

Building on the lessons from pilot programs conducted by CMS and numerous partner organizations, we propose a model PI education curriculum. We recommend optimizing the timing of such a curriculum to reach physicians as early as possible in their careers, to ensure that these skills are a core part of their knowledge set, and to make certain that physicians periodically renew such training. We believe our program is ideal for residents and fellows as part of the standard graduate medical education curriculum. To reach individuals who have completed their formal training, though, we recommend that practicing physicians complete such a program as part of their continuing education requirements and maintenance of state licensure. Efforts to establish such programs therefore could be led by academic medical centers, state medical boards, or medical specialty societies, which in particular could design curricula most applicable to their specialties. Our hope is that numerous organizations will step forward to collaborate in establishing programs suitable for physicians at various points in their careers.

Various stakeholders should contribute to the development of such programs, including physicians with training and experience in medical review; representatives from private and public payers (both federal and state); representatives from organized medicine; hospital compliance staff; billing and coding experts; state medical boards; and law enforcement representatives. To provide a comprehensive curriculum, all stakeholders who are committed to fighting health care fraud and protecting PI must be involved in the curriculum development process.

We divided our model PI education curriculum into three modules. In the following paragraphs, we describe each module and identity the corresponding competencies and learning objectives. For additional details about our curriculum, see Appendix 1.

Module 1: Overview of health care fraud and broader PI issues

This module introduces physicians to the spectrum of PI issues, including waste, abuse, and fraud, with vivid case examples and a discussion of known fraud schemes. The module also includes a discussion of the legal and regulatory considerations for PI issues, including the civil and criminal penalties for fraud. Finally, the module describes the response of health care and law enforcement organizations to these issues to contextualize the daily activities of physicians within the broader PI framework.

Competencies and learning objectives:

- Learn the spectrum of PI issues, including the scope and variety of fraud and common fraud schemes and systemic issues such as conflicts of interest and perverse incentives.
- Learn the legal framework for PI issues.
- Learn how public regulatory agencies, law enforcement, and organized medicine are responding to PI issues.

Module 2: Preventive strategies to improve PI

This module provides physicians with a host of preventive approaches and tools to protect their medical identities, to institute practice safeguards and compliance activities, and to improve their communication with patients about PI issues. This module includes a discussion of a range of practice settings, including the use of midlevel providers, the corporate practice of medicine, practices in academic centers, and the use of alternative payment models.

Competencies and learning objectives:

- Learn the risk factors for and strategies to avoid medical identity theft.
- Learn the key elements of compliance programs to avoid fraudulent or abusive billing.
- Learn how to help patients avoid and identify fraud schemes.
- Learn how to access resources for further education or reporting of PI issues.

Module 3: Documentation and billing best practices

This module specifically addresses documentation and billing issues, with an emphasis on developing best practices and error prevention strategies, as well as understanding the consequences of shortcomings in these areas. The module also addresses the various types of payment and financial audits of physician practices, discussing the differences between them and how they differ from fraud investigations. As in Module 2, special attention is paid to the range of practice settings and major innovations and trends in health care.

Competencies and learning objectives:

- Learn the importance of accurate documentation and billing, including typical issues, relevant fraud schemes, and error prevention strategies.
- Learn about the various payer audits of physician practices and fraud investigations, including potential consequences.
- Learn documentation and billing best practices.

In Conclusion

About 18% of the gross domestic product in the United States is consumed by health care—more than in any other industrialized country—and that number is expected to rise to 20% by 2020.[5] About $765 billion of that spending is lost to waste, including fraud.[8] Resources lost to such PI issues, regardless of the payer, are potentially being diverted from supporting needed health care services. Physicians are the principal gatekeepers who decide when, how, and what health care services are delivered. With so much of our nation's spending at risk, the education of our medical professionals on issues of fraud and PI must be thoughtfully planned and universally delivered.

With this article, we hope to encourage a greater national recognition and sense of urgency regarding the need for physician education in health care fraud and PI. Ideally, this recognition should act as the impetus for leaders to create programs that will support universal physician continuing education. Only through such efforts—as one aspect of a broader detection and prevention strategy—can we reasonably expect to make significant and permanent changes to reduce the impact that fraud, waste, and other PI issues have on the overall cost of health care and, perhaps more importantly, on the experience and safety of patients and providers alike. Educating physicians is an essential step in establishing a broader culture of compliance and improved integrity, extending far beyond Medicare and Medicaid.

Funding/Support: None.

Other disclosures: None.

Ethical approval: Not applicable.

Disclaimer: The views expressed in this article represent the authors' views and not necessarily the views or policies of their respective institutions.

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Appendix 1

A Model Health Care Fraud and Program Integrity (PI) Education Curriculum for Physicians

Topics	Elements
Module 1: Overview of health care fraud and broader PI issues	
Spectrum of PI	• Define spectrum of PI issues: errors, waste, abuse, and fraud • Differentiate mistakes and inefficiencies from intentional deception • Discuss scope of fraud and the extent to which it occurs in Medicare, Medicaid, and private health insurance systems • Discuss potential conflicts of interest and perverse incentives in medicine and impact on physician behavior • May include a general review of public and private payers if necessary
Fraud schemes	• Discuss variety and types of fraud schemes, especially as relevant to practicing clinicians, including medical identify theft; billing for unnecessary services, substandard products, or undelivered products or services; employment of unenrolled or excluded providers; persistent and pervasive up-coding; enabling beneficiary fraud; kickbacks; and fraud in capitated payment models (e.g., withholding of necessary services) • Provide a personal account of medical identity theft or other inadvertent physician involvement, as feasible
Legal context of PI	• Review fraud and abuse laws enforcing PI efforts: False Claims Act, Anti-Kickback Statute, Physician Self-Referral Statute, Exclusion Statute, Civil Monetary Penalties Law • Identify recent cases related to these statutes • Discuss requirements to report and the range of consequences for fraudulent providers
Stakeholder response	• Review efforts by major stakeholders in fraud and PI: payers, law enforcement, clinicians, patients • Describe initiatives particularly relevant to clinician audience
Module 2: Preventive strategies to improve PI	
Protect yourself and your medical identity	• Review scope and examples of physician medical identity theft and how stolen identities are used in fraud schemes • Detail risk factors for medical identity theft • Discuss strategies for avoiding medical identity theft, including security of practice documents and information technology (IT) security • Review additional factors impacting identity security, such as billing reassignment, the corporate practice of medicine, use of midlevel providers, and special issues for academic medical practices
Protect your practice	• Review common fraud schemes involving physician practices • Describe key elements and best practices of compliance programs and internal controls to prevent fraudulent or abusive billing • Discuss special considerations, such as teaching institution practices, use of midlevel providers, health care innovations including novel payment models, the corporate practice of medicine, and fraud and PI issues in managed care • Detail typical practice vulnerabilities that allow patients and physicians to be victimized
Protect your patients	• Review the scope of patient-mediated fraud including patient medical identity theft • Discuss examples of patient medical identity theft and resulting impact, including to medical records • Discuss resources to educate patients about fraud, and acquire tools to help them prevent and detect fraud • Provide a personal patient account of medical identity theft or other inadvertent involvement, as feasible
Report PI issues	• Discuss resources and contacts for clinicians and patients to promote PI and report fraud or identity theft • Review resources for practice compliance programs and voluntary self-reporting of PI issues
Module 3: Documentation and billing best practices	
Billing and documentation fraud	• Detail scope of billing and documentation fraud with relevant examples • Review importance of accurate documentation and billing with respect to patient care, PI, and legal and payer requirements • Identify typical problems with and shortcomings of physician billing and documentation, including preventive strategies • Discuss documentation and billing requirements that may be specific to certain public or private payers, including relevant state variation
Public and private payer audits	• Review various types of public and private payer audits of physician practices: Medicare administrative contractor audits, Medicare and Medicaid recovery audits, error rate audits (e.g., Comprehensive Error Rate Testing [CERT], Medicare; Payment Error Rate Measurement [PERM], Medicaid), state Medicaid agency audits, and risk adjustment data validation (RADV) audits in managed care • Differentiate these audits from fraud investigations, and discuss the main investigative units, such as Medicare zone PI contractors, Medicaid integrity contractors, Department of Health and Human Services Office of Inspector General, and Medicaid fraud control units • Describe key differences between audit types and the potential consequences of audits, including the appeals process • Discuss resources for assistance and guidance in audit response and management
Compliance, oversight, and best practices	• Discuss important elements of good documentation, including sources of information in this area for public and private payers and relevant differences between payers • Describe key elements and best practices of compliance programs and internal controls for billing and documentation, including internal audits and what providers should do if they identify a problem (e.g., return overpayments, self-disclosure protocol) • Review special considerations in documentation, such as use of midlevel providers and clinical practices in teaching institutions • Discuss relevant payment innovations and such major changes as the transition to ICD-10 and the increasing adoption of electronic medical records

Standing Committees, Task Forces and Councils
of the Medical Board of California
February 2014

Committee	*Members*
Executive Committee	**Sharon Levine, M.D., President** David Serrano Sewell, J.D.,Vice President Silvia Diego, M.D., Secretary Dev GnanaDev, M.D. Barbara Yaroslavsky, Past President
Licensing Committee	**Silvia Diego, M.D., Chair** Michael Bishop, M.D. Gerrie Schipske, R.N.P., J.D. Denise Pines Ronald Lewis, M.D. Jamie Wright, Esq.
Enforcement Committee	**Dev GnanaDev, M.D., Chair** Howard Krauss, M.D. Sharon Levine, M.D. Gerrie Schipske, R.N.P., J.D. David Serrano Sewell, J.D. Barbara Yaroslavsky Felix Yip, M.D.
Application Review Committee	**Gerrie Schipske, R.N.P., J.D., Chair** Silvia Diego, M.D. Ronald Lewis, M.D.
Special Faculty Permit Review Committee	**Felix Yip, Chair** Clarence Braddock, M.D. James Nuovo, M.D. (UCD) Neal Cohen, M.D. (UCSF) Neil Parker, M.D. (UCLA) Daniel Giang, M.D. (LLU) Andrew Ries, M.D. (UCSD) John A. Heydt, M.D. (UCR) Frank Sinatra, M.D. (USC) Wadie Najm, M.D. Barbara Yaroslavsky
Special Programs Committee	**Chair (Vacant)**
Access to Care Committee/Cultural and Linguistic Competency Committee ********** **Subcommittee Members**	Barbara Yaroslavsky Elwood Lui ********** David Hayes-Bautista, Ph.D. Sergio Aguilar-Gaxiola, M.D., Ph.D

Education and Wellness Committee ********** **Subcommittee Members**	**Barbara Yaroslavsky, Chair** Silvia Diego, M.D. Howard Krauss, M.D. Denise Pines Gerrie Schipske, R.N.P., J.D. ********** Daniel Giang, M.D. William Norcross, M.D. Laurie Gregg, M.D. Gary Nye, M.D.
Committee on Physician Supervisory Responsibilities	**Gerrie Schipske, R.N.P., J.D. Chair** Suzanne Kilmer, M.D. Christopher Barnard, M.D. James Newman, M.D. Michael Bishop, M.D. Paul Phinney, M.D. Jack Bruner, M.D. Harrison Robbins, M.D. Beth Grivett, P.A.
Midwifery Advisory Council	**Carrie Sparrevohn, L.M., Chair** James Byrne, M.D. Karen Ehrlich, L.M. Tosi Marceline, L.M. Monique Webster Barbara Yaroslavsky
Panel A	**Barbara Yaroslavsky, Chair** Ronald Lewis, M.D., Vice Chair Michael Bishop, M.D. Silvia Diego, M.D. David Serrano Sewell, J.D. Jamie Wright, Esq. Felix Yip, M.D.
Panel B	**Dev GnanaDev, M.D. Chair** Denise Pines, Vice Chair Howard Krauss, M.D. Sharon Levine, M.D. Elwood Lui Gerrie Schipske, R.N.P., J.D.
Organizational Effectiveness Committee	Sharon Levine, M.D.
Legislation Subcommittee	Sharon Levine, M.D.
Prescribing Task Force	Michael Bishop, M.D. Barbara Yaroslavsky
Outpatient Surgery Settings Task Force	Dev. GnanaDev, M.D. David Serrano Sewell

Members of Executive Committee include: President, Vice President, Secretary, Immediate Past President, and one other member appointed by the President. (*note: there should be at least one public member within group of five members)

Revised: February 2014

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: January 22, 2014
ATTENTION: Members, Medical Board of California
SUBJECT: Interim Executive Director Report – Executive Summary
STAFF CONTACT: Kimberly Kirchmeyer, Interim Executive Director

REQUESTED ACTION:
This report is intended to provide the Members with an update on the staffing, budget, and other administrative functions/projects occurring at the Medical Board of California (Board). No action is needed at this time.

Administrative Updates:
Board staff has had several meetings with interested parties regarding the Board.

- Dr. Levine and the Executive Staff continue to have conference calls twice a month to review the actions of the Board and ensure the requests of the Board are being completed. Board Members are receiving monthly updates on activities at the Board as well as a pending projects list.
- Regular meetings continue to be held with Denise Brown, Director of the Department of Consumer Affairs (DCA) and other DCA Executive staff.
- Regular meetings continue to be held with Gloria Castro, Senior Assistant Attorney General.
- Board staff again met with the California Ambulatory Surgery Association regarding the laws and regulations pertaining to outpatient surgery settings and SB 304.
- Board staff met with the University of California, Graduate Medical Education Deans to provide an update on the Board and to assist with any issues that have arisen, including BreEZe, application processing, new laws, etc.
- Board staff and DCA staff have met numerous times to discuss the transition of the Board's investigators to the DCA. The DCA is working on a Memorandum of Understanding based upon input by Board Executive Management.
- Board staff held an "Enforcement Camp" for legislative staff and DCA staff. The attendees heard from Enforcement staff who explained the complaint and investigative process, particularly cases related to overprescribing and unlicensed activity cases. In addition, the attendees heard the process for probation monitoring. The training was all day and provided an overall understanding of the Board and its enforcement processes as well as some of the laws/regulations that hinder or slow down the enforcement process.
- Board staff have been meeting with the DCA and the Department of Justice to discuss requirements for the new CURES database.
- Board staff met with staff from the University of California - Davis, Medical School to discuss accelerated medical school programs.
- Board staff met with staff from the University of California, San Francisco (UCSF) to discuss a supplemental survey to our physician survey that would be sent to licensees at the time of renewal. Board staff has assisted the UCSF in the past in this endeavor and they requested that the Board again include a supplemental survey. Board staff indicated that due to the transition to the BreEZe system, this would not be possible until at least 2015.

Teleconferencing Project Update:
The teleconference project is going to be implemented at the February Board Meeting. The Committee on Physician Supervisory Responsibilities and the Education and Wellness Committee will use the teleconference option. More information as to how this option worked and the amount of callers on the phone during the meetings will be provided verbally under this agenda item. However, staff have been notified that the information provided regarding the cost of this function was quoted to us incorrectly by the vendor. During discussions on this topic, it was indicated that the cost for teleconferencing with 200 callers for a 6-hour meeting would be $1,765.32. However, with the new quote received from the

vendor, a call for the same timeframe and same number of callers would be $13,870.00. Board staff is looking into other options, and will have more information after the two February Committee meetings. The two Committee meetings are only an hour and a half, so the cost will be lower than this for these meetings, but will provide the Board with the information needed to do an analysis of teleconferencing its meetings.

Staffing Update:
The Board is at an 8% vacancy rate which equates to 21 vacant positions. However, of those 21 vacant positions, the Board has 8 individuals either in background, pending a start date, or pending verification of eligibility. Therefore, the Board only has 13 positions that do not have an individual identified for the position. This equates to a **5% vacancy rate** for the Board. The Board staff is making every effort to fill these positions as quickly as possible.

Budget Update:
Included in the Governor's budget released January 9, 2014, was a Budget Change Proposal (BCP) to enhance the Board's Enforcement Program. The BCP, which will now move through the legislative process for final approval, includes funding for the following permanent full-time employees:
1 Investigator, 1 Associate Governmental Program Analyst (AGPA), 2 Staff Services Analysts, and 1 Office Technician. The investigator position is for the Tustin office and the AGPA is for the Board's Expert Reviewer Program. The remaining positions will be used to assist the work of the Central Complaint Unit and the Discipline Coordination Unit.

Additionally, the Governor's budget included a BCP for the BreEZe funding for $1,531,000 for Fiscal Year (FY) 2014/2015 and a BCP for the Midwifery Program to reimburse the Board $13,000, on an ongoing basis, for services provided to this Program. The budget also included a BCP for the transition of the investigators to the DCA pursuant to Senate Bill 304. This BCP would transfer $15,498,000 and 116 positions from the Board to the DCA. The BCP also includes a Career Executive Assignment (CEA) position and the funding ($118,000) in order to provide the review of the enforcement cases, settlement negotiations, liaison with the Attorney General's Office, etc.

The Board's budget documents are attached, beginning on page BRD 8A-4 and continuing to page BRD 8A-13. The Board's fund condition on page BRD 8A-4 projects the Board's fund reserve, at the end of FY 2013/2014, to be at 4.3 months.

The fund condition report indicates that the Board's fund reserve will be negative in FY 2016/2017. However, the Board continues to have two outstanding loans to the General Fund. These loans will be repaid when the Board reaches its minimum mandated level of two months' reserve. Therefore, page BRD 8A-5 shows partial repayment of the outstanding loans in FYs 2015/2016 and 2016/2017. With the repayment of these loans, the Board would remain at its statutory mandate.

It is not prudent at this time to consider any reduction in licensing fees as previously recommended by the Bureau of State Audits. The other element to take into consideration when reviewing the fund condition is that the Board does not know the impact of the transfer of the investigators to the DCA and, therefore, should wait until the transition has been implemented before any decisions can be made on how the Board's budget and fund will be impacted. The Board will continue to monitor its fund to determine any needed changes.

The Board's overall actual expenditures for FY 2013/2014, as of November 30, 2013, can be found on page BRD 8A-6, and pages BRD 8A-7 to 8A-9 show the budget report specifically for licensing, enforcement, and the AG expenditures. Page BRD 8A-13 provides the Board Members' expenditure report as of January 23, 2014.

BreEZe Update:
The Board staff has been using the new BreEZe system since October 8, 2013. Staff has found several defects in the system that have been reported to the DCA and the vendor. Significantly, staff had outstanding requests for changes that were identified prior to implementation but were not fixed prior to the release of BreEZe because they were deemed not detrimental to the Board being able to go live. Board staff has since been asked to prioritize all of these requests into releases. The releases are scheduled for April 2014, August 2014, and later for those that do not fit into these two releases. As these items are fixed, Board staff must test to ensure that the fix resolved the Board's issue. The system will not meet the Board's requirements until all of the fixes have been completed.

Due to the newness of the system and the learning curve, in addition to the workarounds that must be done prior to the system being fixed, there has been an increase in the time to process both applications and complaints. However, Board staff is conducting overtime and looking at other ways to streamline processes in order to be more efficient. Board management is making every effort to mitigate this slowdown in productivity.

In addition, Board staff cannot run many of the reports that are used as management tools to determine work productivity/timeframes. Neither the Licensing Chief's nor the Enforcement Chief's report will include statistics, as they are not available from the BreEZe system. At this time Board staff is focusing on correcting defects in the system to assist the core functions of licensing and enforcement. The current reports that are in the BreEZe system are not capturing all of the data correctly, or do not meet the needs of the Board.

Board staff have rewritten procedural manuals or developed new ones based upon the transition to BreEZe. This has significantly helped staff in transitioning to this system. Additionally, Licensing Managers, specifically, have set up special training for employees in order to assist with the learning curve into this new system.

0758 - Medical Board
Analysis of Fund Condition
(Dollars in Thousands)

		ACTUAL 2012-13	CURRENT YEAR 2013-14	BY 2014-15	BY+1 2015-16	BY+2 2016-17
BEGINNING BALANCE		$ 24,612	$ 26,498	$ 21,141	$ 14,944	$ 7,004
Prior Year Adjustment		$ (38)	$ -	$ -	$ -	$ -
Adjusted Beginning Balance		$ 24,574	$ 26,498	$ 21,141	$ 14,944	$ 7,004
REVENUES AND TRANSFERS						
Revenues:						
125600	Other regulatory fees	$ 365	$ 330	$ 331	$ 288	$ 288
125700	Other regulatory licenses and permits	$ 6,174	$ 5,961	$ 5,961	$ 5,647	$ 5,647
125800	Renewal fees	$ 46,107	$ 45,687	$ 45,727	$ 45,481	$ 45,481
125900	Delinquent fees	$ 94	$ 98	$ 98	$ 98	$ 98
142500	Miscellaneous services to the public	$ 33	$ 30	$ 30	$ 30	$ 30
150300	Income from surplus money investments	$ 98	$ 75	$ 65	$ 63	$ 40
160400	Sale of fixed assets	$ 4	$ 3	$ 3	$ 3	$ 3
161000	Escheat of unclaimed checks and warrants	$ 15	$ -	$ -	$ -	$ -
161400	Miscellaneous revenues	$ 5	$ 16	$ 16	$ 16	$ 16
164300	Penalty assessments - Probation Monitoring		$ 900	$ 900	$ 900	$ 900
Totals, Revenues		$ 52,895	$ 53,100	$ 53,131	$ 52,526	$ 52,503
Transfers:						
TOTALS, REVENUES AND TRANSFERS		$ 52,895	$ 53,100	$ 53,131	$ 52,526	$ 52,503
TOTAL RESOURCES		$ 77,469	$ 79,598	$ 74,272	$ 67,470	$ 59,507
EXPENDITURES						
Disbursements:						
0840 State Controller (State Operations)		$ 34	$ 3	$ -	$ -	$ -
8880 FSCU (State Operations)		$ -	$ -	$ -	$ -	$ -
FISCAL		$ 278	$ 259	$ 48	$ -	$ -
1110 Program Expenditures (State Operations)		$ 50,659	$ 56,167	$ 56,354	$ 58,415	$ 59,625
2013-2014 and 2014-15 Approved Costs						
BreEZe Costs			$ 1,209			
CURES			$ 819	$ 819		
Anticipated Future Costs						
SB 304				$ 118	$ 118	$ 118
Anticipated BreEZe Cost				$ 1,531	$ 1,531	$ 1,531
Establish Spending Authority for Midwifery				$ (13)	$ (13)	$ (13)
Enforcement Enhancements				$ 471	$ 415	$ 415
Totals, Disbursements		$ 50,971	$ 58,457	$ 59,328	$ 60,466	$ 61,676
FUND BALANCE						
Reserve for economic uncertainties		$ 26,498	$ 21,141	$ 14,944	$ 7,004	$ (2,169)
Months in Reserve		5.4	4.3	3.0	1.4	-0.4

NOTES:

A. ASSUMES WORKLOAD AND REVENUE PROJECTIONS ARE REALIZED FOR 2015-16 AND BEYOND.

B. INTEREST ON FUND ESTIMATED AT .361%

$9 million was loaned to the General Fund by the Board in FY 11/12 and $6 million was loaned to the General Fund in FY 08/09. These loans will be repaid when the fund is nearing its minimum mandated level.

1/17/2014

0758 - Medical Board
Analysis of Fund Condition

(Dollars in Thousands)
With General Fund Loan repayment

		ACTUAL 2012-13	CURRENT YEAR 2013-14	BY 2014-15	BY+1 2015-16	BY+2 2016-17
BEGINNING BALANCE		$ 24,612	$ 26,498	$ 21,141	$ 14,944	$ 13,004
Prior Year Adjustment		$ (38)	$ -	$ -	$ -	$ -
Adjusted Beginning Balance		$ 24,574	$ 26,498	$ 21,141	$ 14,944	$ 13,004
REVENUES AND TRANSFERS						
Revenues:						
125600	Other regulatory fees	$ 365	$ 330	$ 331	$ 288	$ 288
125700	Other regulatory licenses and permits	$ 6,174	$ 5,961	$ 5,961	$ 5,647	$ 5,647
125800	Renewal fees	$ 46,107	$ 45,687	$ 45,727	$ 45,481	$ 45,481
125900	Delinquent fees	$ 94	$ 98	$ 98	$ 98	$ 98
142500	Miscellaneous services to the public	$ 33	$ 30	$ 30	$ 30	$ 30
150300	Income from surplus money investments	$ 98	$ 75	$ 65	$ 63	$ 40
160400	Sale of fixed assets	$ 4	$ 3	$ 3	$ 3	$ 3
161000	Escheat of unclaimed checks and warrants	$ 15	$ -	$ -	$ -	$ -
161400	Miscellaneous revenues	$ 5	$ 16	$ 16	$ 16	$ 16
164300	Penalty assessments - Probation Monitoring		$ 900	$ 900	$ 900	$ 900
Totals, Revenues		$ 52,895	$ 53,100	$ 53,131	$ 52,526	$ 52,503
Transfers:						
	Proposed GF Loan Repayment				$ 6,000	$ 7,000
TOTALS, REVENUES AND TRANSFERS		$ 52,895	$ 53,100	$ 53,131	$ 58,526	$ 59,503
TOTAL RESOURCES		$ 77,469	$ 79,598	$ 74,272	$ 73,470	$ 72,507
EXPENDITURES						
Disbursements:						
0840 State Controller (State Operations)		$ 34	$ 3	$ -	$ -	$ -
8880 FSCU (State Operations)		$ -	$ -	$ -	$ -	$ -
FISCAL		$ 278	$ 259	$ 48	$ -	$ -
1110 Program Expenditures (State Operations)		$ 50,659	$ 56,167	$ 56,354	$ 58,415	$ 59,625
	2013-2014 and 2014-15 Approved Costs					
	BreEZe Costs		$ 1,209			
	CURES		$ 819	$ 819		
	Anticipated Future Costs					
	SB 304			$ 118	$ 118	$ 118
	Anticipated BreEZe Cost			$ 1,531	$ 1,531	$ 1,531
	Establish Spending Authority for Midwifery			$ (13)	$ (13)	$ (13)
	Enforcement Enhancements			$ 471	$ 415	$ 415
Totals, Disbursements		$ 50,971	$ 58,457	$ 59,328	$ 60,466	$ 61,676
FUND BALANCE						
Reserve for economic uncertainties		$ 26,498	$ 21,141	$ 14,944	$ 13,004	$ 10,831
Months in Reserve		5.4	4.3	3.0	2.5	2.1

NOTES:

A. ASSUMES WORKLOAD AND REVENUE PROJECTIONS ARE REALIZED FOR 2015-16 AND BEYOND.

B. INTEREST ON FUND ESTIMATED AT .361%

$9 million was loaned to the General Fund by the Board in FY 11/12 and $6 million was loaned to the General Fund in FY 08/09. These loans will be repaid when the fund is nearing its minimum mandated level.

1/17/2014

Medical Board of California
FY 13/14
Budget Expenditure Report
(As of November 30, 2013)
(42% of fiscal year completed)

OBJECT DESCRIPTION	BUDGET ALLOTMENT	EXPENSES/ ENCUMB	PERCENT OF BUDGET EXP/ENCUMB	UNENCUMB BALANCE
PERSONAL SERVICES				
Salary & Wages				
(Staff & Exec Director)	16,540,850	6,544,420	39.6	9,996,430
Board Members	31,500	18,600	59.0	12,900
Phy Fitness Incentive Pay	29,623	6,275	21.2	23,348
Temp Help	1,800,000	427,090	23.7	1,372,910
Overtime	50,000	38,566	77.1	11,434
Staff Benefits	8,328,522	3,206,341	38.5	5,122,181
BL 12-03 Blanket	0	19,732		0
TOTALS, PERS SERVICES	26,780,495	10,261,024	38.3	16,539,203
OPERATING EXP & EQUIP				
General Expense	300,535	357,261	118.9	(56,726)
Fingerprint Reports	333,448	111,128	33.3	222,320
Minor Equipment	24,300	21,945	90.3	2,355
Printing	435,755	97,218	22.3	338,537
Communications	257,190	68,413	26.6	188,777
Postage	182,511	72,558	39.8	109,953
Insurance	41,053	0	0.0	41,053
Travel In-State	361,298	65,962	18.3	295,336
Travel Out-of-State	7,000	402	5.7	6,598
Training	78,895	15,128	19.2	63,767
Facilities Operation (Rent)	2,490,025	2,406,581	96.6	83,444
Consult/Prof Services	2,198,594	1,595,327	72.6	603,267
Departmental Prorata	5,034,442	2,420,203	48.1	2,614,239
Interagency Services	5,142	0	0.0	5,142
Consolidated Data Center	650,230	223,958	34.4	426,272
Data Processing	129,492	189,694	146.5	(60,202)
Central Admin Svcs (Statewide Prorata)	2,417,774	1,208,887	50.0	1,208,887
Attorney General Services	13,347,280	6,463,988	48.4	6,883,292
Office of Administrative Hearings	1,525,080	270,122	17.7	1,254,958
Evidence/Witness	1,893,439	629,860	33.3	1,263,579
Court Reporter Services	225,000	206,955	92.0	18,045
Major Equipment	392,120	128,827	32.9	263,293
Other Items of Expense	81	30,379	37,504.9	(30,298)
Vehicle Operations	247,925	96,641	39.0	151,284
Court-ordered Payments	0	992		(992)
Board of Control Claim	0	0		0
TOTALS, OE&E	32,578,609	16,682,429	51.2	15,896,180
TOTALS, EXPENDITURES	59,359,104	26,943,453	45.4	32,415,651
Scheduled Reimbursements	(384,000)	(263,986)	68.7	(120,014)
Distributed Costs	(780,000)	(209,243)	26.8	(570,757)
NET TOTAL, EXPENDITURES	58,195,105	26,470,224	45.5	31,724,880
Unscheduled Reimbursements		(213,404)		
		26,256,820		

Budget Expenditure Report.xls
Date:1/17/14

MEDICAL BOARD OF CALIFORNIA
ENFORCEMENT PROGRAM
BUDGET REPORT
JULY 1, 2013- NOVEMBER 30, 2013

	FY 13/14 BUDGET	EXPENDITURES/ ENCUMBRANCES YR-TO-DATE	LAG TIME (MONTHS)
PERSONAL SERVICES			
Salaries & Wages	10,926,314	4,205,423	current
Staff Benefits	4,869,104	1,881,971	current
TOTAL PERSONAL SERVICES	15,795,418	6,087,394	
OPERATING EXPENSE & EQUIPMENT			
General Expense/Fingerprint Reports	144,768	275,152	1-2
Printing	157,926	66,634	1-2
Communications	127,358	46,722	1-2
Postage	69,500	23,079	1-2
Insurance	38,235	0	current
Travel In-State	229,018	39,262	1-2
Travel Out-State	7,000	402	1-2
Training	31,000	2,845	1-2
Facililties Operations	1,922,825	1,727,540	current
Consultant/Professional Services	300,000	248,515	1-2
Departmental Services	3,440,033	1,724,849	current
Interagency Services	3,629	0	1-2
Data Processing	18,000	38,903	1-2
Statewide Pro Rata	1,652,065	852,628	current
Attorney General 1/	13,157,280	6,450,249	current
OAH	1,525,080	270,122	1
Evidence/Witness Fees	1,820,939	614,706	1-2
Court Reporter Services	224,750	206,955	1-2
Major Equipment	0	128,827	1-2
Other Items of Expense (Law Enf. Materials/Lab, etc.)	81	29,951	1-2
Vehicle Operations	206,925	83,101	1-2
Minor Equipment	0	11,999	1-2
Court-Ordered Payments	0	0	current
TOTAL OPERATING EXPENSES & EQUIPMENT	25,076,412	12,842,441	
DISTRIBUTED COSTS	(744,054)	(200,188)	
TOTAL BUDGET/EXPENDITURES	**40,127,776**	**18,729,647**	
Unscheduled Reimbursements		(45,232)	
		18,684,415	

1/See next page for monthly billing detail

MEDICAL BOARD OF CALIFORNIA
ATTORNEY GENERAL EXPENDITURES - FY 13/14
DOJ AGENCY CODE 003573 - ENFORCEMENT (6303)

		Number of Hours	Rate	Amount
July	Attorney Services	6,177.00	170.00	1,050,090.00
	Paralegal Services	289.25	120.00	34,710.00
	Auditor/Analyst Services	273.75	99.00	27,101.25
	Cost of Suit			0.00
				1,111,901.25
August	Attorney Services	5,997.25	170.00	1,019,532.50
	Paralegal Services	302.00	120.00	36,240.00
	Auditor/Analyst Services	233.75	99.00	23,141.25
	Cost of Suit			5,311.65
				1,084,225.40
September	Attorney Services	5,722.50	170.00	972,825.00
	Paralegal Services	294.50	120.00	35,340.00
	Auditor/Analyst Services	167.25	99.00	16,557.75
	Cost of Suit			1,885.50
				1,026,608.25
October	Attorney Services	7,124.50	170.00	1,211,165.00
	Paralegal Services	323.00	120.00	38,760.00
	Auditor/Analyst Services	224.50	99.00	22,225.50
	Cost of Suit			2,035.55
				1,274,186.05
November	Attorney Services	5,473.75	170.00	930,537.50
	Paralegal Services	174.25	120.00	20,910.00
	Auditor/Analyst	169.25	99.00	16,755.75
	Cost of Suit			11,674.85
				979,878.10
December	Attorney Services	5,547.00	170.00	942,990.00
	Paralegal Services	111.75	120.00	13,410.00
	Auditor/Analyst	153.75	99.00	15,221.25
	Cost of Suit			1,828.29
				973,449.54
			Total July-Dec =	**6,450,248.59**
			FY 13/14 Budget =	**13,157,280.00**

MEDICAL BOARD OF CALIFORNIA
LICENSING PROGRAM
BUDGET REPORT
JULY 1, 2013 - NOVEMBER 30, 2013

	FY 13/14 BUDGET	EXPENDITURES/ ENCUMBRANCES YR-TO-DATE	LAG TIME (MONTHS)
PERSONAL SERVICES			
Salaries & Wages	2,776,800	1,082,179	current
Staff Benefits	1,303,330	510,898	current
TOTAL PERSONAL SERVICES	4,080,130	1,593,077	
OPERATING EXPENSES & EQUIPMENT			
General Expense	47,000	1,250	1-2
Fingerprint Reports*	333,448	110,901	1-2
Printing	99,876	16,308	1-2
Communications	32,246	5,125	1-2
Postage	100,000	49,123	1-2
Travel In-State	9,758	2,958	1-2
Training	8,500	0	1-2
Facilities Operation	226,000	247,488	current
Consult/Professional Services	1,810,873	1,343,124	1-2
Departmental Services	697,774	269,642	current
Interagency Services	587	0	current
Data Processing	4,000	503	1-2
Statewide Pro Rata	335,103	138,296	current
Attorney General	190,000	13,739	current
Evidence/Witness Fees	7,500	0	1-2
Court Reporter Services	250	0	1-2
Major Equipment	0	0	1-2
Minor Equipment	0	866	1-2
TOTAL OPERATING EXPENSES & EQUIPMENT	3,902,915	2,199,323	
SCHEDULED REIMBURSEMENTS	(384,000)	(263,887)	
DISTRIBUTED COSTS	(31,131)	(6,345)	
TOTAL BUDGET/EXPENDITURES	**7,567,914**	**3,522,168** **	

*Department of Justice invoices for fingerprint reports, name checks, and subsequent arrest reports
** Includes Polysom
1/17/2014

MEDICAL BOARD OF CALIFORNIA BUDGET OVERVIEW BY BOARD COMPONENT

	EXEC	ENFORCE	OPERATION SAFE MEDICINE	LICENSING	ADMIN SERVICES	INFO SYSTEMS	PROBATION MONITORING	BOARD TOTAL
FY 10/11								
$ Budgeted	1,944,000	37,720,000	577,000	5,045,000	1,688,000	3,118,000	1,735,000	51,827,000
$ Spent *	1,771,000	34,420,000	651,000	5,061,000	1,564,000	2,948,000	487,000	46,902,000 *
Positions Authorized	8.8	165.0	6.0	52.3	15.0	17.0	25.0	289.1
FY 11/12								
$ Budgeted	1,885,220	40,510,088		5,336,015	1,585,554	3,069,028	2,013,445	54,399,350
$ Spent *	1,775,576	33,754,208		4,745,127	1,543,636	2,810,667	503,487	45,132,701 *
Positions Authorized	8.8	164.1		53.3	15.0	17.0	25.0	283.2
FY 12/13								
$ Budgeted	2,132,008	39,300,606	525,515	6,399,247	1,570,587	3,754,162	2,239,391	55,921,516
$ Spent*	1,762,058	37,058,493	672,700	5,770,689	1,671,010	3,001,574	720,484	50,657,008 *
Positions Authorized	8.8	147.0	6.0	53.3	14.0	17.0	25.0	271.1
FY 13/14								
$ Budgeted	2,304,466	40,127,776	716,147	7,567,914	1,833,855	3,363,720	2,281,227	58,195,105
$ Spent thru 11/30*	658,686	18,684,415	391,415	3,522,168	710,984	1,507,785	781,367	26,256,820 *
Positions Authorized	8.8	147.0	6.0	53.3	14.0	17.0	25.0	271.1

* net expenditures (includes unscheduled reimbursements)

1/17/2014
Budget Overview by Program.xls

ENFORCEMENT/PROBATION RECEIPTS
MONTHLY PROFILE: JULY 2011 - JUNE 2014

	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11	Jan-12	Feb-12	Mar-12	Apr-12	May-12	Jun-12	FYTD Total
Invest Cost Recovery	300	350	300	100	50	3,932	40,589	50	10,281	0	0	0	55,952
Criminal Cost Recovery	0	0	150	0	50	250	605	504	1,055	754	14,147	2,558	20,073
Probation Monitoring	42,542	41,848	44,639	105,369	96,368	109,993	343,253	222,925	83,025	97,287	59,217	34,113	1,280,578
Exam	1,639	777	2,481	627	1,692	2,552	977	1,106	6,495	1,831	6,024	2,224	28,424
Cite/Fine	200	4,350	800	10,650	3,250	6,400	8,650	7,002	3,450	7,825	3,075	3,800	59,452
MONTHLY TOTAL	44,681	47,325	48,370	116,745	101,409	123,127	394,074	231,587	104,307	107,698	82,462	42,695	1,444,479
FYTD TOTAL	44,681	92,005	140,375	257,120	358,530	481,657	875,730	1,107,317	1,211,624	1,319,322	1,401,784	1,444,479	

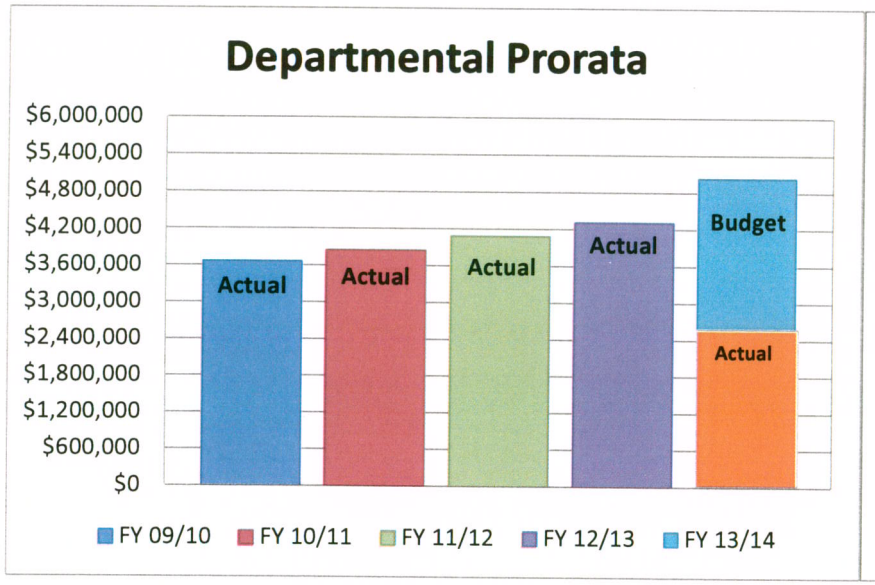
	Jul-12	Aug-12	Sep-12	Oct-12	Nov-12	Dec-12	Jan-13	Feb-13	Mar-13	Apr-13	May-13	Jun-13	FYTD Total
Invest Cost Recovery	250	300	650	2,349	750	700	4,527	600	2,595	6,888	600	500	20,709
Criminal Cost Recovery	1,409	705	619	5,136	964	10,914	2,411	1,198	676	489	39,422	2,871	66,814
Probation Monitoring	38,879	47,871	26,432	65,999	45,648	146,950	434,545	319,499	52,448	55,458	29,123	33,854	1,296,706
Exam	1,848	3,456	6,563	2,666	5,212	975	3,074	1,625	4,725	12,262	138	1,881	44,424
Cite/Fine	2,800	1,900	4,750	6,268	8,586	12,300	8,700	4,059	3,850	1,650	3,100	7,300	65,263
MONTHLY TOTAL	45,186	54,232	39,014	82,418	61,160	171,839	453,257	326,981	64,294	76,747	72,382	46,406	1,493,916
FYTD TOTAL	45,186	99,418	138,432	220,850	282,010	453,849	907,106	1,234,087	1,298,381	1,375,128	1,447,510	1,493,916	

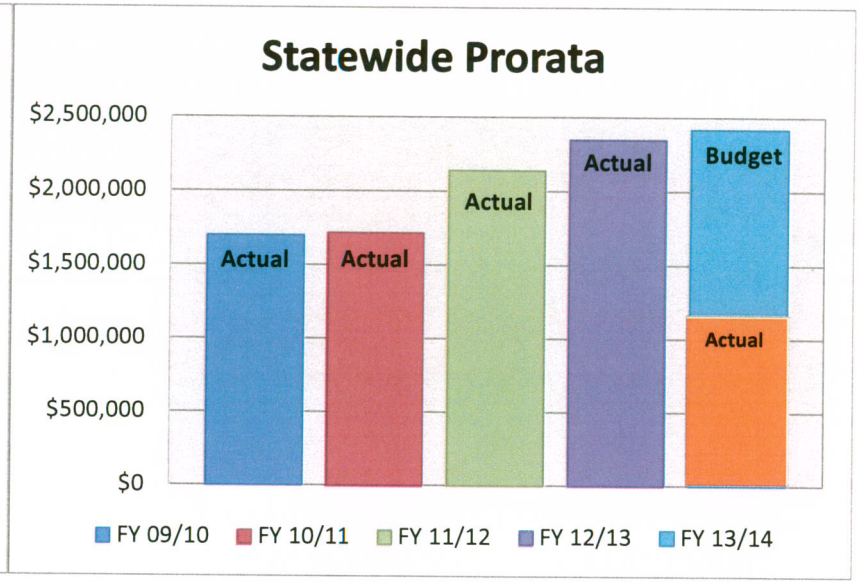
	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	Apr-14	May-14	Jun-14	FYTD Total
Invest Cost Recovery	650	550	550	0	0	50							1,800
Criminal Cost Recovery	499	698	1,050	3,127	8,857	204							14,435
Probation Monitoring	69,560	54,598	28,303	0	100,901	115,137							368,499
Exam	7,232	6,164	4,537	0	5,568	1,500							25,001
Cite/Fine	2,850	5,450	2,000	4,925	2,975	2,850							21,050
MONTHLY TOTAL	80,791	67,460	36,440	8,052	118,301	119,741	0	0	0	0	0	0	430,784
FYTD TOTAL	80,791	148,251	184,691	192,743	311,044	430,784	430,784	430,784	430,784	430,784	430,784	430,784	

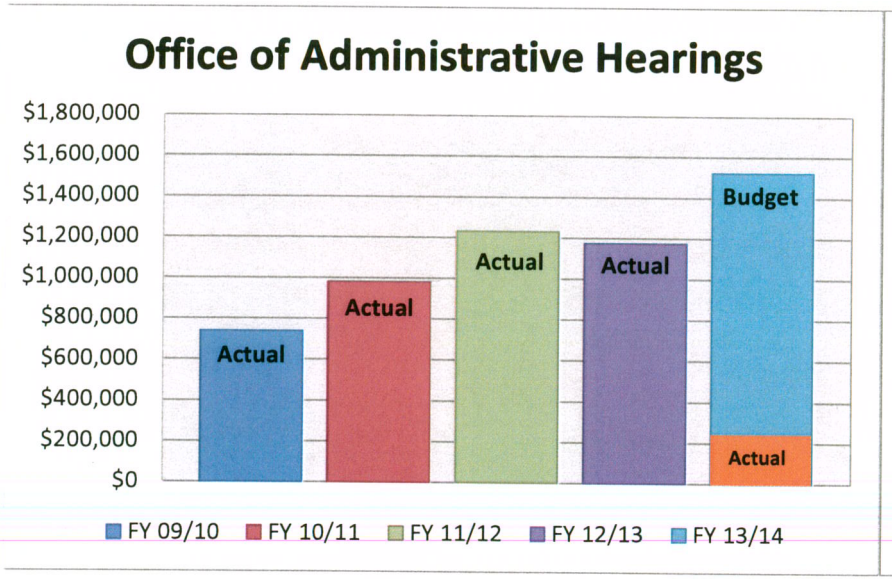
excel:enfreceiptsmonthlyprofile.xls.revised 1/14/2014

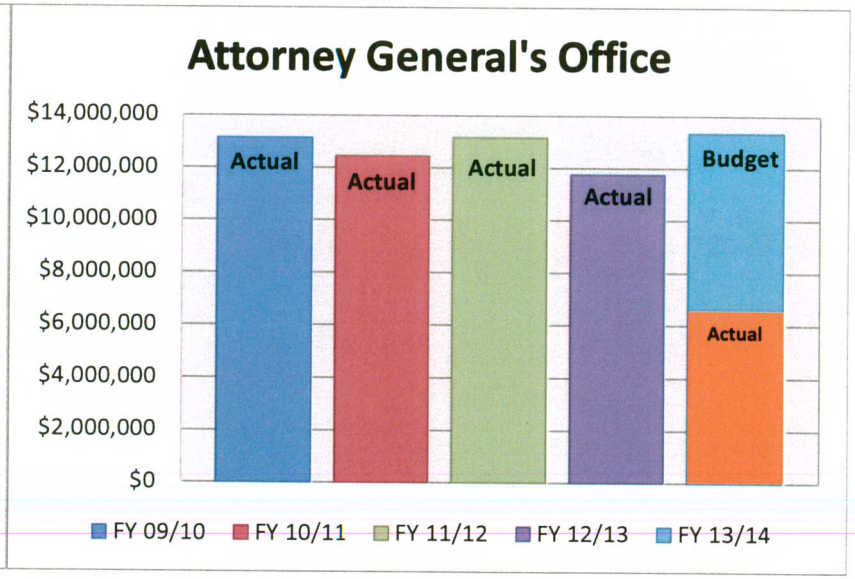
NOTE: Payment amounts for October, November, and December reflect payments made directly to MBC; they do not include payments made through BreEZe online system. Online payment information is unavailable.

Strategic Plan Objective 5.3
External Agencies' Spending









Board Members' Expenditures - Per Diem/Travel
July 1, 2013 - June 30, 2014

NAMES	JULY	AUG	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APRIL	MAY	JUNE	YTD
DR. BISHOP - Per diem	$ 600.00	$ 400.00	$ 600.00	$ 600.00	$ 500.00	$ 500.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,200.00
Travel	$ 799.36		$ 698.96	$ 464.02	$ -		$ -	$ -	$ -	$ -	$ -	$ -	$ 1,962.34
	$ 1,399.36	$ 400.00	$ 1,298.96	$ 1,064.02	$ 500.00	$ 500.00	$ -	$ -	$ -	$ -	$ -	$ -	**$ 5,162.34**
DR. DIEGO - Per diem	$ 500.00	$ 1,700.00	$ -	$ 1,700.00	$ 1,400.00	$ 1,300.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 6,600.00
Travel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	$ 500.00	$ 1,700.00	$ -	$ 1,700.00	$ 1,400.00	$ 1,300.00	$ -	$ -	$ -	$ -	$ -	$ -	**$ 6,600.00**
DR GNANADEV - Per diem	$ 900.00	$ 1,300.00	$ 1,100.00	$ 900.00	$ 800.00	$ 1,200.00	$ -	$ -	$ -	$ -			$ 6,200.00
Travel	$ 521.96			$ -	$ -	$ -	$ -	$ -					$ 521.96
	$ 1,421.96	$ 1,300.00	$ 1,100.00	$ 900.00	$ 800.00	$ 1,200.00	$ -	$ -	$ -	$ -	$ -	$ -	**$ 6,721.96**
DR. KRAUSS - Per diem	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Travel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	**$ -**
DR. LEVINE - Per diem	$ -	$ -	$ -			$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Travel	$ 477.16		$ -		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 477.16
	$ 477.16	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	**$ 477.16**
DR. LEWIS - Per diem	$ -	$ -	$ -	$ 1,000.00	$ 700.00	$ 1,300.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,000.00
Travel	$ -	$ -	$ 416.26	$ 389.08	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 805.34
	$ -	$ -	$ 416.26	$ 1,389.08	$ 700.00	$ 1,300.00	$ -	$ -	$ -	$ -	$ -	$ -	**$ 3,805.34**
MR. LUI - Per diem	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Travel	$ -	$ -	$ -	$ -	$ 564.87	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 564.87
	$ -	$ -	$ -	$ -	$ 564.87	$ -	$ -	$ -	$ -	$ -	$ -	$ -	**$ 564.87**
MS. PINES - Per diem	$ 1,500.00	$ 1,400.00	$ 1,200.00	$ 1,500.00	$ 1,200.00	$ 1,000.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 7,800.00
Travel	$ 771.58	$ -	$ -	$ 254.32		$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 1,025.90
	$ 2,271.58	$ 1,400.00	$ 1,200.00	$ 1,754.32	$ 1,200.00	$ 1,000.00	$ -	$ -	$ -	$ -	$ -	$ -	**$ 8,825.90**
DR. SALOMONSON - Per diem	$ 200.00	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 200.00
Travel	$ 679.36	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 679.36
	$ 879.36	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	**$ 879.36**
MS.SCHIPSKE - Per diem	$ 1,100.00	$ 1,000.00	$ 1,200.00	$ 1,200.00	$ -	$ 900.00	$ -	$ -	$ -	$ -	$ -		$ 5,400.00
Travel	$ 742.37	$ -	$ -	$ 277.41	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 1,019.78
	$ 1,842.37	$ 1,000.00	$ 1,200.00	$ 1,477.41	$ -	$ 900.00	$ -	$ -	$ -	$ -	$ -	$ -	**$ 6,419.78**
MR. SERRANO SWELL- Per diem	$ 800.00	$ 500.00	$ 700.00	$ 800.00	$ 500.00	$ 600.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,900.00
	$ -	$ -	$ -	$ 783.34	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 783.34
	$ 800.00	$ 500.00	$ 700.00	$ 1,583.34	$ 500.00	$ 600.00	$ -	$ -	$ -	$ -	$ -	$ -	**$ 4,683.34**
MS.WRIGHT - Per diem	$ -	$ -	$ 300.00	$ 1,200.00	$ 900.00	$ 1,000.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,400.00
Travel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
													$ 3,400.00
MS. YAROSLAVSKY - Per diem	$ 1,300.00	$ 600.00	$ 800.00	$ -	$ -	$ 1,000.00	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,700.00
Travel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	$ 1,300.00	$ 600.00	$ 800.00	$ -	$ -	$ 1,000.00	$ -	$ -	$ -	$ -	$ -	$ -	**$ 3,700.00**
DR. YIP - Per diem	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Travel	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	**$ -**

As of: 1/23/2014

TOTAL PER DIEM	$43,400.00
TOTAL TRAVEL	$ 7,840.05
TOTAL	**$ 51,240.05**

UPDATED SB 304 Implementation Plan

October 2013

1. Appear at the Medical Board of California's (MBC) next board meeting and jointly present a proposed transition plan. **(COMPLETE)**
2. Establish with MBC and Department of Consumer Affairs (DCA) budget staff the details of the budget in implementing SB 304. **(COMPLETE – See attached Budget Fact Sheet)**
3. Transition Team is created (DCA Exec staff and MBC). **(COMPLETE)**

November 2013

1. Begin joint meetings with MBC, Health Quality Enforcement Section of the Attorney General's (AG) Office (HQES) and the Division of Investigation (DOI) Re: briefing on Vertical Enforcement Prosecution (VEP). **(COMPLETE)**
2. Identify Transaction areas: **(COMPLETE)**
   - Facilities (if any)
   - Human Resources (HR)/Personnel
   - Budgets and Contracts
   - Expectations of AG's Office/HQES
   - Review current organization charts and begin discussion on proposed charts
   - Information Technology (IT) needs (databases, case management)
   - Internal and external communication
3. Begin informal meet and greets with MBC staff transitioning to DOI-HQIU. **(COMPLETE)**

December 2013

1. Continue discussions on VEP manual. **(IN PROCESS)**
2. Request delegation from California Department of Human Resources (CalHR) to meet and confer with affected labor groups. **(COMPLETE)**
3. Hold meetings between DCA, DOI and MBC staff regarding specific transaction areas. **(COMPLETE)**

January 2014

1. SB 304 becomes law (transfers the MBC peace officers, medical consultants and support staff to D of I effective July 1, 2014). **(COMPLETE)**
2. Governor's Budget for FY 2014/15 is introduced. **(COMPLETE)**
3. Finish meet and greets with MBC staff. **(COMPLETE)**
4. Transition team continues to meet with HQES to define implementation of VEP in the SB 304 model. **(IN PROCESS)**
5. Begin information sharing meetings with unions. **(IN PROCESS)**
6. Begin drafting Memorandum of Understanding between DCA and MBC re: Transition of MBC Investigators. **(IN PROCESS)**
7. Begin regular meetings among DCA and MBC staff on specific issue areas. **(IN PROCESS)**

February 2014

1. Attend MBC's regular meeting to provide update. **(COMPLETE)**
2. Develop plan for the transition of IT, facilities, contracts and other administrative support components. **(COMPLETE)**
3. Initiate joint (DOI/MBC) senior management introductions and facilitate internal communication meetings.
4. Complete MOU between DCA and MBC.

March 2014

1. Continue implementation of IT, facilities, contracts, and other administrative support components. This includes regular meetings and updates between MBC and DCA staff.
2. Continue information sharing meetings with unions.

April 2014

1. Review and determine need for revisions or amendments to the current VEP manuals of the MBC and HQES. **(IN PROCESS)**
2. Formal Meet and Confer (after Governor's Budget).
3. Hold Townhall for MBC and DOI staff regarding the Transition.

May 2014

1. FY 2014/15 budget hearings begin.
2. Implement IT system access for DOI's management (case management systems).
3. Attend MBC's regular meeting and provide update.

June 2014

1. FY 2014/15 Budget Bill enacted to reflect appropriate budget authority.
2. Continue information sharing meetings with unions, if necessary.

July 2014

1. MBC investigators, support staff and medical consultants become employees of the DOI.
2. Initiate a plan to have monthly conference calls or quarterly meetings with HQES leadership.
3. Report to MBC on the Transition.

October 2014

1. Provide enforcement statistics to MBC at regular meeting.

Health Quality Investigation Unit
Budget Fact Sheet

Senate Bill 304 (Lieu, Chapter 515, Statutes of 2013) requires all peace officers, field office medical consultants, and their support positions to be transferred from the Medical Board of California (MBC) to the Health Quality Investigation Unit (HQIU) within the Division of Investigation no later than July 1, 2014.

- FY 2014/15 Appropriation: $15.628 million
  - $12.896 million for personal services.
  - $2.732 million for operating expenses and equipment (Includes one-time costs for equipment).
- FY 2014/15 Authorized Positions: 117.0
  - 97.0 sworn peace offices and 20.0 non-sworn positions.
  - 12.0 positions will report to 1747 N. Market Blvd instead of 2005 Evergreen St.
  - Remaining positions will continue to report to existing offices.
- FY 2014/15 Investigative Services
  - HQIU will track investigative hours for the allied health programs (excludes MBC).
  - Allied health programs will be billed at the existing MBC hourly rate.
  - MBC will fully reimburse HQIU for all costs incurred.
  - Allied health programs will reimburse MBC for their costs (HQIU will handle the accounting process).
- Potential Changes to Investigative Services
  - HQIU, MBC, and the allied health programs will work in conjunction to update the investigative services cost methodology for the HQIU. Any change to this methodology would become effective in FY 2015-16.

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: January 21, 2014
ATTENTION: Board Members
SUBJECT: Executive Summary - Enforcement
STAFF CONTACT: Renee Threadgill, Chief of Enforcement

Program Update:

There are currently 938 experts in our expert database. 406 experts were utilized to review 727 cases in calendar year 2013. **Attachment A** provides the Expert Reviewer Program statistics.

Additional experts are needed in the following specialties:

- Pain Medicine
- Addiction Medicine
- Psychiatry
- Neurosurgery

There are currently 6 sworn investigator vacancies (8% vacancy rate). However, 2 of those positions have individuals who are in background for the vacancy (which reduces the investigator vacancy rate to 5%). There are 2 Supervising Investigator vacancies (10% vacancy rate). The overall vacancy rate for all sworn positions is 8% or 6%, if the vacancies with candidates in background are eliminated.

The Central Complaint Unit received 3,707 complaints in the first two quarters of fiscal year 2012/2013. However, it received 3,952 complaints in the first two quarters of the current fiscal year (2013/2014). If this pattern of increased complaints continues, the complaint intake for this year will be 1,000 more complaints than received in the previous fiscal year.

In January, the investigators received outstanding training that was organized by the Board's training unit and focused on various aspects of prescription drug investigations (search warrants; undercover operations; pharmacy records; and drug profiles). The training was approved by POST for training credits.

The statistical data routinely provided is not available due to the transition to the BreEZe system.

CASES BY SPECIALTY SENT FOR REVIEW
UTILIZATION OF EXPERTS BY SPECIALTY
ACTIVE LIST EXPERTS BY SPECIALTY
January 1, 2014

SPECIALTY	**Number of cases sent to Experts / reviewed (Jan-Dec, 2013)**	**Number of Experts Utilized (January-December, 2013)**	**Active List Experts 938**
ADDICTION	14	**7 EXPERTS** 4 LIST EXPERTS REVIEWED 1 CASE 2 LIST EXPERTS REVIEWED 2 CASES 1 LIST EXPERT REVIEWED 6 CASES	16
ALLERGY & IMMUNOLOGY (A&I)			4
ANESTHESIOLOGY (Anes)	24	**19 EXPERTS** 12 LIST EXPERTS REVIEWED 1 CASE 5 LIST EXPERTS REVIEWED 2 CASES 2 LIST EXPERTS REVIEWED 3 CASES	68 ↓
COLON & RECTAL SURGERY (CRS)	6	**2 EXPERTS** 1 LIST EXPERT REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 5 CASES	3
COMPLEMENTARY/ALTERNATIVE MEDICINE	19	**9 EXPERTS** 4 LIST EXPERTS REVIEWED 1 CASE 2 LIST EXPERTS REVIEWED 2 CASES 1 LIST EXPERT REVIEWED 3 CASES 2 LIST EXPERTS REVIEWED 4 CASES	20 ↓
CORRECTIONAL MEDICINE	1	**1 EXPERT** 1 LIST EXPERT	27 ↓
DERMATOLOGY (D)	1	**1 EXPERT** 1 LIST EXPERT	11 ↑
EMERGENCY (EM)	22	**18 EXPERTS** 13 LIST EXPERTS REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 2 CASES 4 LIST EXPERTS REVIEWED 3 CASES	48 ↓
FAMILY (FM) *involved companion cases and included physical evaluations	109	**47 EXPERTS** 21 LIST EXPERTS REVIEWED 1 CASE 10 LIST EXPERTS REVIEWED 2 CASES 6 LIST EXPERTS REVIEWED 3 CASES 1 LIST EXPERT REVIEWED 4 CASES 2 LIST EXPERTS REVIEWED 5 CASES* 3 LIST EXPERTS REVIEWED 6 CASES* 1 LIST EXPERT REVIEWED 7 CASES* 2 LIST EXPERTS REVIEWED 8 CASES* 1 LIST EXPERT REVIEWED 10 CASES*	68 ↓

CASES BY SPECIALTY SENT FOR REVIEW
UTILIZATION OF EXPERTS BY SPECIALTY
ACTIVE LIST EXPERTS BY SPECIALTY
January 1, 2014

SPECIALTY	Number of cases sent to Experts / reviewed (Jan-Dec, 2013)	Number of Experts Utilized (January-December, 2013)	Active List Experts 938
INTERNAL (General Internal Med) *companion cases and included physical evaluations as well as preparation/testimony of cases previously reviewed	101	**52 EXPERTS** 35 LIST EXPERTS REVIEWED 1 CASE 4 LIST EXPERTS REVIEWED 2 CASES 4 LIST EXPERTS REVIEWED 3 CASES 5 LIST EXPERTS REVIEWED 4 CASES 1 LIST EXPERT REVIEWED 5 CASES* 1 LIST EXPERT REVIEWED 9 CASES* 1 LIST EXPERT REVIEWED 10 CASES* 1 LIST EXPERT REVIEWED 13 CASES*	184 ↑
Cardiovascular Disease (Cv)	18	**9 EXPERTS** 1 LIST EXPERT REVIEWED 1 CASE 4 LIST EXPERTS REVIEWED 2 CASES 3 LIST EXPERTS REVIEWED 3 CASES 1 LIST EXPERT REVIEWED 4 CASES	33 ↑
Gastroenterology (Ge)	8	**8 EXPERTS** 7 LIST EXPERTS REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 2 CASES	17 ↓
Medical Oncology (Onc)	5	**4 EXPERTS** 3 LIST EXPERTS REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 2 CASES	12 ↑
Nephrology (Nep)	1	**1 EXPERT** 1 LIST EXPERT	8 ↑
Rheumatology (Rhu)	1	**2 EXPERTS** 2 LIST EXPERTS REVIEWED 1 CASE	8
MIDWIFE REVIEWER	1	**1 EXPERT** 1 LIST EXPERT	6
NEUROLOGICAL SURGERY (NS) *short list of reviewers	21	**7 EXPERTS** 2 LIST EXPERTS REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 2 CASES 2 LIST EXPERTS REVIEWED 4 CASES 1 LIST EXPERT REVIEWED 5 CASES* 1 LIST EXPERT REVIEWED 6 CASES*	8 ↓
NEUROLOGY (N)	18	**10 EXPERTS** 4 LIST EXPERTS REVIEWED 1 CASE 3 LIST EXPERTS REVIEWED 2 CASES 3 LIST EXPERTS REVIEWED 3 CASES	23 ↓

CASES BY SPECIALTY SENT FOR REVIEW
UTILIZATION OF EXPERTS BY SPECIALTY
ACTIVE LIST EXPERTS BY SPECIALTY
January 1, 2014

SPECIALTY	**Number of cases sent to Experts / reviewed (Jan-Dec, 2013)**	**Number of Experts Utilized (January-December, 2013)**	**Active List Experts 938**
NEUROLOGY with Special Qualifications in Child Neurology (N/ChiN)			2
NUCLEAR MEDICINE (NuM)			5
OBSTETRICS & GYNECOLOGY (ObG) *short list of reviewers (actively practicing)	72	**35 EXPERTS** 15 LIST EXPERTS REVIEWED 1 CASE 11 LIST EXPERTS REVIEWED 2 CASES 1 LIST EXPERT REVIEWED 3 CASES 4 LIST EXPERTS REVIEWED 4 CASES 2 LIST EXPERTS REVIEWED 7 CASES* 2 LIST EXPERTS REVIEWED 8 CASES*	75 ↓
OCCUPATIONAL MEDICINE	4	**1 EXPERT** 1 LIST EXPERT REVIEWED 4 CASES	8
OPHTHALMOLOGY (Oph) *involved companion cases	15	**11 EXPERTS** 1 OFF LIST EXPERT REVIEWED 1 CASE 8 LIST EXPERTS REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 3 CASES 1 LIST EXPERT REVIEWED 6 CASES*	30 ↓
ORAL & MAXILLOFACIAL SURGERY	1	**1 EXPERT** 1 LIST EXPERT	1
ORTHOPAEDIC SURGERY (OrS)	21	**14 EXPERTS** 8 LIST EXPERTS REVIEWED 1 CASE 3 LIST EXPERTS REVIEWED 2 CASES 2 LIST EXPERTS REVIEWED 3 CASES 1 LIST EXPERT REVIEWED 4 CASES	26 ↑
OTOLARYNGOLOGY (Oto)	3	**3 EXPERTS** 3 LIST EXPERTS REVIEWED 1 CASE	19

CASES BY SPECIALTY SENT FOR REVIEW
UTILIZATION OF EXPERTS BY SPECIALTY
ACTIVE LIST EXPERTS BY SPECIALTY
January 1, 2014

SPECIALTY	Number of cases sent to Experts / reviewed (Jan-Dec, 2013)	Number of Experts Utilized (January-December, 2013)	Active List Experts 938
PAIN MEDICINE (PM) *short list of reviewers	73	**22 EXPERTS** 8 LIST EXPERTS REVIEWED 1 CASE 4 LIST EXPERTS REVIEWED 2 CASES 2 LIST EXPERTS REVIEWED 3 CASES 2 LIST EXPERTS REVIEWED 5 CASES 2 LIST EXPERTS REVIEWED 6 CASES* 2 LIST EXPERTS REVIEWED 7 CASES* 2 LIST EXPERTS REVIEWED 9 CASES*	15 ↓
PATHOLOGY (Path)	6	**3 EXPERTS** 2 LIST EXPERTS REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 4 CASES	9
PEDIATRICS (Ped)	8	**8 EXPERTS** 5 LIST EXPERTS REVIEWED 1 CASE 2 LIST EXPERTS REVIEWED 2 CASES 1 LIST EXPERT REVIEWED 3 CASES	46
PHYSICAL MEDICINE & REHABILITATION (PMR)	2	**2 EXPERTS** 1 LIST EXPERT REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 2 CASES	8 ↓
PLASTIC SURGERY (PIS) *involved companion cases	40	**19 EXPERTS** 10 LIST EXPERTS REVIEWED 1 CASE 4 LIST EXPERTS REVIEWED 2 CASES 1 LIST EXPERT REVIEWED 3 CASES 1 LIST EXPERT REVIEWED 4 CASES 1 LIST EXPERT REVIEWED 5 CASES* 1 LIST EXPERT REVIEWED 6 CASES* 1 LIST EXPERT REVIEWED 8 CASES*	52 ↑

CASES BY SPECIALTY SENT FOR REVIEW
UTILIZATION OF EXPERTS BY SPECIALTY
ACTIVE LIST EXPERTS BY SPECIALTY
January 1, 2014

SPECIALTY	Number of cases sent to Experts / reviewed (Jan-Dec, 2013)	Number of Experts Utilized (January-December, 2013)	Active List Experts 938
PSYCHIATRY (Psyc) *included case reviews, evaluations and preparation/testimony (of cases previously reviewed)	132	**60 EXPERTS** 34 LIST EXPERTS REVIEWED 1 CASE 7 LIST EXPERTS REVIEWED 2 CASES 7 LIST EXPERTS REVIEWED 3 CASES 2 LIST EXPERTS REVIEWED 4 CASES 3 LIST EXPERTS REVIEWED 5 CASES* 3 LIST EXPERTS REVIEWED 6 CASES* 1 LIST EXPERT REVIEWED 7 CASES* 1 LIST EXPERT REVIEWED 8 CASES* 1 LIST EXPERT REVIEWED 9 CASES* 1 LIST EXPERT REVIEWED 10 CASES*	82 ↑
RADIOLOGY (Rad)	9	**7 EXPERTS** 5 LIST EXPERTS REVIEWED 1 CASE 2 LIST EXPERTS REVIEWED 2 CASES	35
RADIATION ONCOLOGY	2	**1 EXPERT** 1 LIST EXPERT REVIEWED 2 CASES	4
SLEEP MEDICINE (S)	1	**1 EXPERT** 1 LIST EXPERT	8
SURGERY (S)	39	**23 EXPERTS** 11 LIST EXPERTS REVIEWED 1 CASE 9 LIST EXPERTS REVIEWED 2 CASES 2 LIST EXPERTS REVIEWED 3 CASES 1 LIST EXPERT REVIEWED 6 CASES	41 ↓
Vascular Surgery (VascS)	3	**2 EXPERTS** 1 LIST EXPERT REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 2 CASES	8
THORACIC SURGERY (TS)	5	**5 EXPERTS** 3 LIST EXPERTS REVIEWED 1 CASE 1 LIST EXPERT REVIEWED 2 CASES 1 LIST EXPERT REVIEWED 3 CASES	15 ↓
(*MEDICAL) TOXICOLOGY*	1	**1 EXPERT** 1 LIST EXPERT	3

CASES BY SPECIALTY SENT FOR REVIEW
UTILIZATION OF EXPERTS BY SPECIALTY
ACTIVE LIST EXPERTS BY SPECIALTY
January 1, 2014

SPECIALTY	Number of cases sent to Experts / reviewed (Jan-Dec, 2013)	Number of Experts Utilized (January-December, 2013)	Active List Experts 938
UROLOGY (U) *short list of reviewers	22	**10 EXPERTS** 5 LIST EXPERTS REVIEWED 1 CASE 2 LIST EXPERTS REVIEWED 2 CASES 1 LIST EXPERT REVIEWED 3 CASES 1 LIST EXPERT REVIEWED 5 CASES* 1 LIST EXPERT REVIEWED 6 CASES*	17

TOTAL CASES SENT: Calendar Year 2013	**727**
TOTAL LIST EXPERTS UTILIZED: Calendar Year 2013	**406**
TOTAL ACTIVE LIST EXPERTS as of 12/31/2013	**938**

Expert Program/sg (12/31/13)

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED:	January 21, 2014
ATTENTION:	Board Members
SUBJECT:	Rewrite of SB 1441 Uniform Standards Regarding Substance-Abusing Healing Arts Licensees
FROM:	Kerrie Webb, Senior Staff Counsel

REQUESTED ACTION:

Review the proposed regulatory language, comments to the original proposed regulation, and staff's responses to those comments to determine if further edits need to be made.

BACKGROUND:

During the 45-day public-comment period of the rulemaking process for implementation of SB 1441 Uniform Standards Regarding Substance-Abusing Licensees, the Board received several meritorious comments on the proposed language. Additionally, a hearing was held at the October 2013 Board meeting, and further public comment was received. Following the public-comment period, significant proposed changes have been made to the draft language, and the rewrite is submitted now for review under attachment 13A. This report highlights the major changes reflected in the proposed language.

First, the proposed language drew comments that demonstrated it was difficult for readers to follow to ensure that the regulation contained the required provisions under SB 1441. Therefore, the first major change is that the language has been renumbered and reworded to conform more closely with the SB 1441 provisions, where appropriate. Please note that Uniform Standards 1, 2, and 6 are combined under 1361.5 (c)(1) (dealing with Clinical Diagnostic Evaluations and Reports; Temporary Removal From Practice) for clarity in the Board's disciplinary orders.

A second major change is that certain provisions required under SB 1441, but not appropriate to include in a disciplinary order, have been included under new proposed regulatory sections. For example, it was determined that the reporting requirements from Uniform Standards 4 and 16 were not appropriate to include in a disciplinary order, as they were directives to the Board, and not to the licensee. The absence of the reporting requirements in the prior proposed language drew negative comments from the public. Under the new rewrite, the reporting requirements are included, but in a separate proposed regulation, 16 CCR 1361.55, which is now part of this rulemaking file, and subject to public comment.

Similarly, because these standards instruct the Board, as opposed to the licensee, on actions to be taken or requirements to be met, Uniform Standards 8 and 9 (Results of Biological Fluid Tests), 10 (Actions by Licensees and Consequences Thereof), 11 (Request to Return to Full or Partial Practice), and certain provisions of 4 and 13 (Requirements for Laboratories/Testing Locations and Specimen Collectors for Testing Substance-Abusing Licensees) are included in separate proposed sections. Thus, the Board would be required to comply with these sections, but they would not needlessly appear in a licensee's disciplinary order.

Third, the Board received comments from several professional associations and consumer groups seeking technical changes to improve the regulatory language. Each Member received a copy of all written comments. A summary of each comment and a proposed response has been prepared for the Board's review, and is attached under 13B. Those proposed changes requested through public comment, and recommended by staff for adoption by the Board, have been incorporated into the rewrite of the regulations for consideration.

Finally, there are some Uniform Standards that staff deems are not appropriate for the Board to include at this time, namely 12, dealing with an informal process for reinstatement, a mechanism that this Board does not have, and most of 13, and 14 and 15, dealing with private-sector vendors not used by this Board. At a later point, if the Board amends the disciplinary guidelines to include an informal process for reinstatement, or monitoring by a vendor, then, at that same time, the Board would have to adopt the Uniform Standards dealing with that area.

AMENDED PROPOSED REGULATIONS FOR IMPLEMENTATION OF UNIFORM STANDARDS REGARDING SUBSTANCE-ABUSING HEALING ARTS LICENSEES (SB 1441)

Modified Text

Changes to the modified proposed language as presented on October 25, 2013, are identified by red underline for new text and ~~blue double strikethrough~~ for new deleted text. Additionally, new regulatory sections are identified by highlighting.

Article 4
Disciplinary Guidelines and Uniform Standards for Substance-Abusing Licensees

1. Section 1361 of Title 16 of the California Code of Regulations is amended to read:

Section 1361. Disciplinary Guidelines and Exceptions for Uniform Standards Related to Substance-Abusing Licensees.

(a) In reaching a decision on a disciplinary action under the Administrative Procedures Act (Government Code Section 11400 et seq.), the Medical Board of California shall consider the disciplinary guidelines entitled "Manual of Model Disciplinary Order and Disciplinary Guidelines With Model Language" (11th Edition/2011) which are hereby incorporated by reference. Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the ~~Medical~~ Board ~~of California~~ in its sole discretion, determines that the facts of the particular case warrant such deviation – for example: the presence of mitigating factors; the age of the case; evidentiary problems.

(b) Notwithstanding subsection (a), the Board shall use the **U**niform **S**tandards for **S**ubstance-**A**busing **L**icensees as provided in Section 1361.5, without deviation, for each individual determined to be a substance-abusing licensee.

(c) Nothing in this section or section 1361.5 shall be construed as a limitation on the Board's authority to seek an interim suspension order against a licensee pursuant to section 11529 of the Government Code.

2. Section 1361.5 is added to Title 16 of the California Code of Regulations to read:

1361.5. Uniform Standards for Substance-Abusing Licensees.

(a) If the licensee is to be disciplined~~,~~ for unprofessional conduct involving the use of illegal drugs, the abuse of drugs and/or alcohol or ~~both,~~ the use of another prohibited substance as defined herein, the licensee shall be presumed to be a substance-abusing licensee for purposes of section 315 of the Code. ~~The terms and conditions specified in subsection (c) shall be used in any probationary order of the Board affecting that licensee.~~

(b) Nothing in this section shall prohibit the Board from imposing additional terms or conditions of probation that are specific to a particular case or that are derived from the Board's disciplinary guidelines referenced in Section 1361 in any order that the Board determines ~~would provide greater~~ is necessary for public protection or to enhance the rehabilitation of the licensee.

(c) The following probationary terms and conditions, if ordered, shall be used without deviation in the case of a substance-abusing licensee:

~~(1) Notice of Employment Information. If a licensee whose license is on probation has an employer, the licensee shall provide to the Board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent for the Board and his or her employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.~~

(1) Clinical Diagnostic Evaluations and Reports; Temporary Removal From Practice.

(A) If the Board orders a licensee who is on probation due to a substance abuse problem to undergo a clinical diagnostic evaluation, the following applies:

(i) The clinical diagnostic evaluation shall be conducted by a licensed physician and surgeon who holds a valid, unrestricted license, has three (3) years' experience in providing evaluations of physicians and surgeons with substance abuse disorders, and is approved by the Board.

(ii) The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.

(iii) The evaluator shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. The evaluator shall provide an objective, unbiased, and independent evaluation.

(iv) The clinical diagnostic evaluation report shall set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem; whether the licensee is a threat to himself or herself or others; and recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and ability to practice safely. If the evaluator determines during the evaluation process that a licensee is a threat to himself or herself or others, the evaluator shall notify the Board within 24 hours of such a determination.

(v) In formulating his or her opinion as to whether the licensee is safe to return to either part-time or full-time practice, and what restrictions or recommendations should be imposed, including participation in an inpatient or outpatient treatment program, the evaluator shall consider the following factors:

(1) License type;
(2) Licensee's history;
(3) Documented length of sobriety/time that has elapsed since substance use;
(4) Scope and pattern of substance abuse;

(5) Treatment history;
(6) Medical history;
(7) Current medical condition;
(8) Nature, duration and severity of substance abuse problem; and
(9) Whether the licensee is a threat to himself or herself or the public.

(vi) The cost of an evaluation shall be borne by the licensee.

(vii) For all evaluations, a final written report shall be provided to the Board no later than ten (10) days from the date the evaluator is assigned the matter. If the evaluator requests additional information or time to complete the evaluation and report, an extension may be granted, but shall not exceed 30 days from the date the evaluator was originally assigned the matter.

(B) Whenever the Board orders a licensee to undergo a clinical diagnostic evaluation, the Board shall order the licensee to cease practice pending the results of the clinical diagnostic evaluation and review by the Board.

(C) While awaiting the results of the clinical diagnostic evaluation, the licensee shall undergo random biological fluid testing at least two (2) times per week.

(D) The Board shall review the clinical diagnostic evaluation report within five (5) business days of receipt to determine whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations shall be imposed on the licensee based on the recommendations made by the evaluator. No licensee shall be returned to practice until he or she has at least 30 days of negative biological fluid tests.

~~(2) Clinical Diagnostic Evaluations and Reports.~~
~~(A) Whenever a licensee on probation due to a substance abuse problem is ordered to undergo a clinical diagnostic evaluation, the evaluator shall be a licensed physician and surgeon who holds a valid, unrestricted license to conduct clinical diagnostic evaluations, has three (3) years' experience in providing evaluations of physicians and surgeons with substance abuse disorders, and is approved by the Board. The evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations. The evaluator shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. The evaluator shall provide an objective, unbiased, and independent evaluation. The cost of an evaluation shall be borne by the licensee.~~

~~(B) For a licensee who undergoes a clinical diagnostic evaluation, the Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the Board.~~

~~(C) While awaiting the results of the clinical diagnostic evaluation, the licensee shall be randomly drug tested~~ **~~undergo random biological fluid testing~~** ~~at least two (2) times per week.~~

~~(D) The clinical diagnostic evaluation report shall set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem, whether the licensee is a threat to himself or herself~~

~~or others, and recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice. If the evaluator determines during the evaluation process that a licensee is a threat to himself or herself or others, the evaluator shall notify the Board within 24 hours of such a determination. In determining whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations should be imposed, including participation in an inpatient or outpatient treatment program, the evaluator shall consider the following factors:~~

~~(i) License type, licensee's history, documented length of sobriety, scope and pattern of substance abuse, treatment history, medical history, current medical condition, nature, duration and severity of substance abuse problem, and whether the licensee is a threat to himself or herself or others.~~

~~(E) For all evaluations, a final written report shall be provided to the Board no later than ten (10) days from the date the evaluator is assigned the matter, unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.~~

~~(F) The Board shall review the clinical diagnostic evaluation report to determine whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations shall be imposed on the licensee based on the recommendations made by the evaluator.~~ ~~**No licensee shall be returned to practice until he or she has at least 30 days of negative biological fluid tests.**~~

(2) Notice of Employer or Supervisor Information. If a licensee whose license is on probation has an employer or supervisor, the licensee shall provide to the Board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent for the Board, the worksite monitor, and his or her employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring. For purposes of this section, "supervisors" shall include the Chief of Staff and the Health or Well Being Committee Chair, or equivalent, if applicable, when the licensee has medical staff privileges.

~~(3) Worksite Monitor Requirements and Responsibilities.~~
~~(A) If the Board determines that a worksite monitor is necessary for a particular licensee, the licensee shall, within 30 calendar days of the effective date of that determination, submit to the Board or its designee for prior approval the names of a worksite monitor(s). The worksite monitor shall meet the following criteria to be approved by the Board:~~

~~(i) The worksite monitor shall not have a current or former financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the Board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the Board; however, under no circumstances shall a licensee's worksite monitor be an employee or supervisee of the licensee.~~

~~(ii) The worksite monitor's license scope of practice shall include the scope of practice of the~~

~~licensee who is being monitored or be another physician and surgeon if no monitor with like scope of practice is available.~~

~~(iii) The worksite monitor shall have an active unrestricted license with no disciplinary action within the last five (5) years.~~

~~(B) The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and agrees to monitor the licensee as set forth by the Board.~~

~~(C) The worksite monitor shall adhere to the following required methods of monitoring the licensee:~~

~~(i) Have face-to-face contact with the licensee in the work environment on as frequent a basis as determined by the Board but not less than once per week.~~

~~(ii) Interview other staff in the office regarding the licensee's behavior, if requested by the Board.~~

~~(iii) Review the licensee's work attendance.~~

~~(D) The worksite monitor shall verbally report any suspected substance abuse to the Board and the licensee's employer within one (1) business day of occurrence. If the suspected substance abuse does not occur during the Board's normal business hours, the verbal report shall be made to the Board within one (1) hour of the next business day. A written report that includes the date, time, and location of the suspected abuse, the licensee's actions and any other information deemed important by the worksite monitor shall be submitted to the Board within 48 hours of the verbal report.~~
~~(E) The worksite monitor shall complete and submit a written report monthly or as directed by the Board. The report shall include: the licensee's name; license number; the worksite monitor's name and signature; worksite monitor's license number; worksite location(s); the dates licensee had face-to-face contact with monitor; worksite staff interviewed, if applicable; attendance report; any change in behavior and/or personal habits; any indicators that can lead to suspected substance abuse.~~

~~(F) The licensee shall execute agreements with the approved worksite monitor(s) and the Board authorizing the Board and worksite monitor to exchange information.~~

~~(G) If the monitor resigns or is no longer available, licensee shall, within 5 calendar days of such resignation or unavailability, submit to the Board the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If licensee fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, licensee shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. Licensee shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.~~

(3) Biological Fluid Testing.

(A) The Board shall require biological fluid testing of substance-abusing licensees.

(B) For the purposes of this section, the terms "biological fluid testing" and "testing" mean the acquisition and chemical analysis of a licensee's urine, blood, breath, or hair.

(C) The Board may order a licensee to undergo a biological fluid test on any day, at any time, including weekends and holidays. Additionally, the licensee shall be subject to 52 - 104 random tests per year within the first year of probation, and 36 - 104 random tests per year for the duration of the probationary term, up to five (5) years. If there has been no positive biological fluid tests in the previous five (5) consecutive years of probation, testing may be reduced to one (1) time per month.

(D) Nothing precludes the Board from increasing the number of random tests for any reason, in addition to ordering any other disciplinary action that may be warranted.

(E) The scheduling of biological fluid testing shall be done on a random basis, preferably by a computer program, except when testing on a specific date is ordered by the Board or its designee.

(F) The licensee shall be required to make daily contact with the Board or its designee to determine if biological fluid testing is required. The licensee shall be tested on the date of the notification as directed by the Board or its designee.

(G) Prior to changing testing locations for any reason, including during vacation or other travel, alternative testing locations must be approved by the Board, and meet the requirements set forth in Section 1361.52.

(H) The cost of biological fluid testing shall be borne by the licensee.

(I) Exceptions to Testing Frequency Schedule.

(i) Previous Testing Orders/Sobriety. In cases where the Board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing prior to being subject to testing by the Board, the Board may give consideration to that testing in altering the Board's own testing schedule so that the combined testing is equivalent to the requirements of this section.

(ii) Violation(s) Outside of Employment. A licensee whose license is placed on probation for a single conviction or incident or two convictions or incidents, spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass the first-year testing frequency requirements.

(iii) Not Employed in Health Care Field. The Board may reduce the testing frequency to a minimum of 12 times per year for any licensee who is not practicing or working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the Board. Prior to returning to any health care employment, the licensee shall be required to test at the first-year testing frequency requirement for a period of at least 60 days. At such time the person returns to employment in a health care field, if the licensee has not previously met the first-year testing frequency requirement, the licensee shall be required to test at the first-year testing frequency requirement for a full year before he or she may be reduced to testing frequency of at least 36 tests per year.

(iv) Tolling. A Board may postpone all testing for any licensee whose probation is placed in a tolling status while the licensee is not residing in California, provided the overall length of the probationary period is also tolled. A licensee shall notify the Board upon the licensee's return to California and shall be subject to biological fluid testing as provided in this section.

(v) Substance Abuse Disorder Not Diagnosed. In cases where no current substance abuse disorder diagnosis is made, a lesser period of monitoring and biological fluid testing may be adopted by the Board, but not shall not be less than 24 times per year.

(J) Reinstatement of License or Reduction of Penalty. Nothing herein shall limit the Board's authority to reduce or eliminate the penalties herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code section 11522.

(4) Group Support Meetings.
(A) ~~The Board may require a licensee to participate in group support meetings. The Board may impose participation in group support meetings following such recommendation by the evaluator or in a clinical diagnosis report.~~ If the Board requires a licensee to participate in group support meetings, the following shall apply:

~~(B)~~ (i) When determining the frequency of group support meetings to be attended, the Board or the evaluator shall give consideration to the following:
(1) The licensee's history~~,~~;
(2) The documented length of sobriety /time that has elapsed since substance use;
(3) The recommendation of the clinical evaluator~~,~~;
(4) The scope and pattern of use~~,~~;
(5) The licensee's treatment history~~,~~; and
(6) The nature, duration, and severity of substance abuse.

~~(C)~~ (ii) The facilitator of a group support meeting shall conform to the following requirements:

~~(i)~~ (1) He or she shall have a minimum of three (3) years' experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or nationally certified organizations.

~~(ii)~~ (2) He or she shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. A licensee's previous participation in a group support meeting led by the same facilitator does not constitute a current or former financial, personal, or business relationship.

~~(iii)~~ (3) He or she shall provide to the Board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

~~(iv)~~ (4) He or she shall report a licensee's unexcused absence to the Board within 24 hours.

(iii) Any costs associated with attending and reporting on group support meetings shall be borne by the licensee.

~~(5) Biological Fluid Testing. The Board shall require biological fluid testing of substance-abusing licensees.~~

~~(A) For the purposes of this subsection, biological fluid testing means the acquisition and chemical analysis of a licensee's urine, blood, breath, or hair.~~

~~(B) The following standards shall apply to a licensee ordered to undergo biological fluid testing:~~

~~(i) The licensee shall be tested a minimum of 52-104 times per year for the first year of probation and at any time ordered by the Board. After the first year of probation, licensees who are practicing shall be randomly drug tested **undergo random biological fluid testing** at least 36-104 times per year, and at any time as directed by the Board.~~

~~(1) The Board may revise the frequency specified in section (i) upon a determination that the licensee is not currently employed in a health care field, the licensee suffers from a substance use or abuse disorder, or other circumstances in which a revision of the testing frequency would not impair public protection. In no case may the testing frequency be reduced below twenty-four (24) times per calendar year.~~

~~(ii) Drug **Biological fluid** testing may be required on any day, including weekends and holidays. **Prior to vacation or absence, alternative biological fluid testing location(s) must be approved by the Board.**~~

~~(iii) The scheduling of **biological fluid** testing shall be done on a random basis, preferably by a computer program, except when testing on a specific date is ordered by the Board.~~

~~(iv) Licensees shall be required to make daily contact with the Board to ascertain if **biological fluid** testing is required. **Licensees shall be drug tested on the date of notification as directed by the Board.**~~

~~(v) Licensees shall submit to all random and specifically ordered biological fluid tests.~~

~~(vi) The cost of biological fluid testing shall be borne by the licensee.~~

~~(vii) Licensees **shall** may elect to have the tests performed by an entity under contract with **a laboratory or service approved in advance by** the Board or by another entity, provided that the **laboratory or service** entity meets all the following standards:~~

~~(1) Its specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the United States Department of Transportation.~~

~~(2) It conforms to the current United States Department of Transportation Guidelines for Specimen Collection.~~

~~(3) Its testing locations comply with the Urine Specimen Collection Guidelines published by the United States Department of Transportation without regard to the type of test administered.~~

~~(4) The collection of testing specimens shall be observed.~~

~~(5) Its laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.~~

~~(6) Its collection sites submit a specimen to a laboratory within one (1) business day of receipt and all specimens collected shall be subjected to chain of custody procedures. The entity shall process and analyze the specimen and provide legally defensible test results to the Board within seven (7) **business** days of receipt of the specimen. **The Board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.**~~

(5) Worksite Monitor Requirements and Responsibilities.

(A) The Board may require the use of worksite monitors. If the Board determines that a worksite monitor is necessary for a particular licensee, the licensee shall, within 30 calendar days of the effective date of that determination, submit to the Board or its designee for prior approval the name of a worksite monitor. The worksite monitor shall meet the following criteria to be approved by the Board:

(i) The worksite monitor shall not have a current or former financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the Board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the Board; however, under no circumstances shall a licensee's worksite monitor be an employee or supervisee of the licensee.

(ii) The worksite monitor's scope of practice shall include the scope of practice of the licensee being monitored, be another licensed health care professional if no monitor with like scope of practice is available, or, as approved by the Board, be a person in a position of authority who is

capable of monitoring the licensee at work.

(iii) If a licensed professional, the worksite monitor shall have an active unrestricted license with no disciplinary action within the last five (5) years.

(iv) The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and agrees to monitor the licensee as set forth by the Board.

(B) The worksite monitor shall adhere to the following required methods of monitoring the licensee:

(i) Have face-to-face contact with the licensee in the work environment on as frequent a basis as determined by the Board, but not less than once per week.

(ii) Interview other staff in the office regarding the licensee's behavior, if requested by the Board.

(iii) Review the licensee's work attendance.

(C) Reporting by the worksite monitor to the Board shall comply with the following:

(i) The worksite monitor shall verbally report any suspected substance abuse to the Board and the licensee's employer or supervisor as defined in subsection (c)(2) within one (1) business day of occurrence. If the suspected substance abuse does not occur during the Board's normal business hours, the verbal report shall be made to the Board within one (1) hour of the next business day. A written report that includes the date, time, and location of the suspected abuse, the licensee's actions and any other information deemed important by the worksite monitor shall be submitted to the Board within 48 hours of the occurrence, or the next business day.

(ii) The worksite monitor shall complete and submit a written report monthly or as directed by the Board. The report shall include the following:
(1) the licensee's name and license number;
(2) the worksite monitor's name and signature;
(3) the worksite monitor's license number, if applicable;
(4) the worksite location(s);
(5) the dates the licensee had face-to-face contact with the monitor;
(6) the names of worksite staff interviewed, if applicable;
(7) an attendance report;
(8) any change in behavior and/or personal habits; and
(9) any indicators that can lead to suspected substance abuse.

(D) The licensee shall complete any required consent forms and execute agreements with the approved worksite monitor(s) and the Board authorizing the Board and worksite monitor to exchange information.

(E) If the monitor resigns or is no longer available, the licensee shall, within five (5) calendar days of such resignation or unavailability, submit to the Board the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If the licensee fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, the licensee shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. The licensee shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.

(F) Worksite monitoring costs shall be borne by the licensee.

(6) The licensee must remain in compliance with all terms and conditions of probation. If the licensee commits a major or minor violation, as defined in Section 1361.52, the Board will execute the disciplinary actions required by that section, and impose any additional terms or conditions necessary for public protection or to enhance the rehabilitation of the licensee.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

~~(6) Results of Biological Fluid Tests.~~
~~(A) If the results of a biological fluid test indicates that a licensee has used, consumed, ingested or administered to himself or herself a prohibited substance, the Board shall order the licensee to cease practice and instruct the licensee to leave any place of employment where he or she is practicing medicine or providing medical services. The Board shall also immediately notify all the licensee's employers~~**~~, if any, and workplace monitor, if any,~~** ~~that the licensee may not provide medical services or practice medicine while the cease practice order is in effect.~~

~~(B) After the issuance of a cease practice order, the Board shall determine whether the test is in fact evidence of prohibited substance use by consulting with the specimen collector and the laboratory, communicating with the licensee, his or her treating physician(s), other health care provider, or group facilitator, as applicable.~~

~~(C) If no prohibited substance use exists, the Board shall immediately lift the cease practice order.~~

~~(D) For the purposes of this section, "prohibited substance" means an illegal or unlawful drug, a lawful drug not prescribed or ordered by an appropriately licensed health care provider for use by the licensee and approved by the Board, alcohol, or other substance.~~

~~(7) Actions by Licensees and Consequences Thereof.~~
~~(A) A licensee who does any of the following shall be deemed to have committed a major violation of his or her probation:~~

~~(i) Fails to undergo a required clinical diagnostic evaluation;~~

~~(ii) Commits multiple minor violations of probation conditions and terms;~~

~~(iii) Treats a patient or patients while under the influence of drugs or alcohol;~~

~~(iv) Commits any drug or alcohol offense that is a violation of state or federal law or any regulation adopted thereto;~~

~~(v) Fails to undergo biological **fluid** testing when ordered;~~

~~(vi) Uses, consumes, ingests, or administers to himself or herself a prohibited substance;~~

~~(vii) Knowingly uses, makes, alters or possesses any object or product in such a way as to defraud a biological fluid test designed to detect the presence of a prohibited substance.~~

~~(B) If a licensee commits one or more major violation, the Board may take the following actions:~~

~~(i) Issue an immediate cease practice order.~~

~~(ii) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee. Any order issued by the Board pursuant to this subsection may state that the licensee must test negative for at least a month of continuous drug **biological fluid** testing before being allowed to resume practice.~~

~~(iii) Increase the frequency of biological fluid testing.~~

~~(C) A licensee who does any of the following shall be deemed to have committed a minor violation of his or her probation:~~

~~(i) Failure to submit required documentation to the Board in a timely manner;~~

~~(ii) Unexcused absence at required meetings;~~

~~(iii) Failure to contact a worksite monitor as required;~~

~~(iv) Failure to comply with another term or condition of his or her probation that does not impair public safety.~~

~~(D) If a licensee commits one or more minor violations, the Board may take the following actions:~~

~~(i) Issue a cease practice order;~~

~~(ii) Issue a citation and fine.~~

~~(iii) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee.~~

~~(E) Nothing in this section shall be considered a limitation on the Board's authority to revoke the probation of a licensee who has violated a term or condition of that probation.~~

~~(8) Request to Return to Full or Partial Practice.~~
~~(A) Before determining whether to authorize the return to practice after the issuance of a cease practice order or after the imposition of practice restrictions following a clinical diagnostic evaluation, the Board in conjunction with the evaluator shall ensure that the licensee meets the following criteria:~~

~~(i) A demonstration of sustained compliance with his or her current treatment or recovery program, as applicable.~~

~~(ii) A demonstration of the capability to practice medicine safely as evidenced by current worksite monitor reports, evaluations conducted by licensed health care practitioners, and any other information relating to the licensee's substance abuse and recovery therefrom.~~

~~(iii) Negative drug **biological fluid** screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of probation.~~

3. Section 1361.51 is added to Title 16 of the California Code of Regulations to read:

1361.51 Results of Biological Fluid Tests of Substance-Abusing Licensees.

(a) If the results of a biological fluid test indicate that a licensee has used, consumed, ingested or administered to himself or herself a prohibited substance, the Board shall order the licensee to cease practice and instruct the licensee to leave any place of work where he or she is practicing medicine or providing medical services. The Board shall also immediately notify all of the licensee's employers, and supervisors as defined under Section 1361.5(c)(2), if any, and work site monitor, if any, that the licensee may not provide medical services or practice medicine while the cease-practice order is in effect.

(b) A biological fluid test will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

(c) After the issuance of a cease-practice order, the Board shall determine whether the positive biological fluid test is in fact evidence of prohibited substance use by consulting with the specimen collector and the laboratory, communicating with the licensee, his or her treating physician(s), other health care provider, or group facilitator, as applicable.

(d) If no prohibited substance use exists, the Board shall lift the cease-practice order within one (1) business day.

(e) For the purposes of this Article, "prohibited substance" means an illegal drug, a lawful drug not prescribed or ordered by an appropriately licensed health care provider for use by the licensee and approved by the Board, alcohol, or other substance the licensee has been instructed

by the Board not to use, consume, ingest, or administer to himself or herself.

(f) If the Board confirms that a positive biological fluid test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Section 1361.52, and the Board shall impose any or all of the consequences set forth in Section 1361.52, in addition to any other terms or conditions the Board determines are necessary for public protection or to enhance the rehabilitation of the licensee.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

4. Section 1361.52 is added to Title 16 of the California Code of Regulations to read:

1361.52 Actions by Substance-Abusing Licensees and Consequences Thereof.

(a) A licensee who does any of the following shall be deemed to have committed a major violation of his or her probation:

(1) Fails to undergo a required clinical diagnostic evaluation;

(2) Commits multiple minor violations of probation conditions and terms;

(3) Treats a patient or patients while under the influence of a prohibited substance;

(4) Engage in any drug or alcohol related act that is a violation of state or federal law or regulation;

(5) Fails to undergo biological fluid testing when ordered;

(6) Uses, consumes, ingests, or administers to himself or herself a prohibited substance;

(7) Knowingly uses, makes, alters or possesses any object or product in such a way as to defraud, or attempt to defraud, a biological fluid test designed to detect the presence of a prohibited substance; or

(8) Fails to comply with any term or condition of his or her probation that impairs public safety.

(b) If a licensee commits a major violation, the Board will take one or more of the following actions:

(1) Issue an immediate cease-practice order.

(2) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee. Any order issued by the Board pursuant to this subsection may state that the licensee must test

negative for at least a month of continuous biological fluid testing before being allowed to resume practice.

(3) Increase the frequency of biological fluid testing.

(4) Refer the licensee for further disciplinary action, such as suspension, revocation, or other action as determined by the Board.

(c) A licensee who does any of the following shall be deemed to have committed a minor violation of his or her probation:

(1) Fails to submit required documentation to the Board in a timely manner;

(2) Has an unexcused absence at a required meeting;

(3) Fails to contact a worksite monitor as required; or

(4) Fails to comply with any term or condition of his or her probation that does not impair public safety.

(d) If a licensee commits a minor violation, the Board will take one or more of the following actions:

(1) Issue a cease-practice order;

(2) Order practice limitations;

(3) Order or increase supervision of licensee;

(4) Order increased documentation;

(5) Issue a citation and fine, or a warning letter;

(6) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee;

(7) Take any other action as determined by the Board.

(E) Nothing in this section shall be considered a limitation on the Board's authority to revoke the probation of a licensee who has violated a term or condition of that probation.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

5. Section 1361.53 is added to Title 16 of the California Code of Regulations to read:

1361.53 Request by a Substance-Abusing Licensee to Return to Practice.

(a) Before determining whether to authorize the return to practice after the issuance of a cease-practice order or after the imposition of practice restrictions following a clinical diagnostic evaluation, the Board in conjunction with the evaluator shall ensure that the licensee meets the following criteria:

(1) A demonstration of sustained compliance with his or her current treatment or recovery program, as applicable;

(2) A demonstration of the capability to practice medicine safely as evidenced by current worksite monitor reports (if currently being monitored), evaluations conducted by licensed health care practitioners, and any other information relating to the licensee's substance abuse and recovery therefrom; and

(3) Negative biological fluid testing reports for at least six (6) months, two (2) positive worksite monitor reports (if currently being monitored), and complete compliance with other terms and conditions of probation.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

6. Section 1361.54 is added to Title 16 of the California Code of Regulations to read:

1361.54 Requirements for Laboratories/Testing Locations and Specimen Collectors for Testing Substance-Abusing Licensees.

(a) Licensees shall contract with a laboratory or service approved in advance by the Board, provided that the laboratory or service meets all the following standards:

(1) Its specimen collectors shall either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the United States Department of Transportation.

(2) Its specimen collectors shall conform to the current United States Department of Transportation Specimen Collection Guidelines.

(3) Its testing locations shall comply with the Urine Specimen Collection Guidelines published by the United States Department of Transportation without regard to the type of test administered.

(4) Its specimen collectors shall observe the collection of testing specimens.

(5) Its laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

(6) Its testing locations shall submit a specimen to a laboratory within one (1) business day of receipt and all specimens collected shall be handled pursuant to chain of custody procedures. The laboratory shall process and analyze the specimen and provide legally defensible test results to the Board within seven (7) business days of receipt of the specimen. The Board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

(7) Its testing locations shall possess all the materials, equipment and technical expertise necessary in order to test every licensee for which it is responsible on any day of the week.

(8) Its testing locations shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.

(9) It must have testing sites that are located throughout California.

(10) It must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the licensee to check in daily for testing.

(11) It must have a secure, HIPAA-compliant website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

(12) It shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory biological fluid test results, medical histories, and any other information relevant to biomedical information.

(13) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

7. Section 1361.55 is added to Title 16 of the California Code of Regulations to read:

1361.55 Reporting Requirements Relating to Substance-Abusing Licensees.

(a) The Board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are on probation:

(1) Number of probationers whose conduct was related to a substance abuse problem;
(2) Number of relapses (break in sobriety);
(3) Number of cease-practice orders;
(4) Number of suspensions;
(5) Number of major violations; nature of violation and action taken;
(6) Number of petitions to revoke probation filed; and
(7) Number of licensees who successfully completed probation.

(b) For each reporting category described in subsection (a), the Board shall identify the licensing category, and the specific substance abuse problem (i.e., cocaine, alcohol, Demorol, etc.).

(c) If the reporting data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of terms and conditions of probation. The information may also be used to determine the risk factor when the Board is determining whether a license should be revoked or placed on probation.

(d) The Board shall use the following criteria to determine if its terms and conditions of probation protects patients from harm and is effective in assisting its licensees in recovering from substance abuse problems in the long term:

(1) One hundred percent of licensees whose licenses were placed on probation as a result of a substance abuse problem successfully completed probation, or had their licenses to practice revoked or surrendered on a timely basis based on noncompliance with terms and conditions of probation.

(2) At least 75 percent of licensees who successfully completed probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

(e) For purposes of measuring outcomes and effectiveness relating to biological fluid testing as described in Section 1361.5(c)(3), the Board shall collect and report historical data (as available) and post-implementation data as follows:

(1) Historical Data. The Board should collect the following historical data (as available) for a period of two years prior to implementation of the Uniform Standards for Substance-Abusing Licensees, for each person subject to testing for banned substances, who has done any of the following:

(A) Tested positive for a banned substance;
(B) Failed to appear or call in for testing on more than three occasions;
(C) Failed to pay testing costs; or
(D) Given a diluted or invalid specimen.

(2) Post implementation Data – Three Years

The Board shall collect data annually for a period of three years following implementation of the Uniform Standards for Substance-Abusing Licensees for every licensee subject to testing for banned substances pursuant to Section 1361.5(c)(3). The data collected shall be reported to the Department of Consumer Affairs and the Legislature, upon request, and shall include, but may not be limited to:

(A) Licensee identification;
(B) License type;
(C) Probation effective date;
(D) General range of testing frequency for each licensee;
(E) Dates testing requested;
(F) Dates tested;
(G) Identity of the entity that performed each test;
(H) Date(s) licensee tested positive;
(I) Date(s) Board was informed of positive test(s);
(J) Date(s) of questionable tests (e.g. dilute, high levels);
(K) Date(s) Board was notified of questionable test(s);
(L) Identification of substances detected or questionably detected;
(M) Date(s) licensee failed to appear for testing;
(N) Date(s) Board notified of licensee's failure to appear;
(O) Date(s) licensee failed to call in for testing;
(P) Date(s) Board was notified that licensee failed to call in for testing;
(Q) Date(s) licensee failed to pay for testing;
(R) Date(s) licensee was removed/suspended from practice (identify which); and
(S) Final outcome and effective date (if applicable).

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018 of the Business and Professions Code. Reference: Sections 315, 315.2, and 315.4 of the Business and Professions Code.

Suggested Responses to Comments Received During the 45-day Comment Period and at the October 25, 2013 Hearing on Regulations to Implement SB 1441 – Uniform Standards for Substance-Abusing Licensees

1. **Comments by Shannon K Robinson, M.D.**

Comment 1.1 – Shannon K. Robinson, M.D., stated that the proposed regulation does not provide clear timelines for the Board to complete adjudication, which can result in physicians continuing to work when they could still be doing harm to patients, or, alternatively, the physician may not be working, and may not be able to get a job while waiting for the Board's decision.

Suggested Response 1.1 – Staff recommends rejecting this comment, as Dr. Robinson is directing her comments to the enforcement timelines that take place before the imposition of disciplinary action. The proposed regulations come into play after a determination has been made that discipline as a substance-abusing licensee is warranted.

2. **Comments by the California Medical Association (CMA) and California Academy of Family Physicians (CAFP) (where they joined CMA's Comments)**

Comment 2.1 –CMA and CAFP expressed concern about the directive to promulgate regulations to implement the SB 1441 standards, which they say are unnecessarily punitive, can further limit access to care by qualified physicians, and which were not developed through a standard regulatory process with full public comment and review by the appropriate state agencies. CMA stated that "Approving regulations simply because they are based on standards developed by another state agency without regard to whether the regulations would be appropriate for physicians and surgeons would not protect consumers and potentially would violate the APA." This was reiterated by Yvonne Choong for CMA at the hearing.

Suggest Response 2.1 – Staff recommends rejecting this comment. While the Board is required by statute to promulgate these regulations, the Board is not simply doing a blanket adoption of regulations developed by another state agency. The Board is engaging in open, public debate about the proposed regulations, and is tailoring the provisions to be workable for the Board and its licensees. Provisions that are not currently applicable to the Board, i.e., those that deal with vendors, are not included in the draft regulations.

Comment 2.2 - CMA and CAFP asked that, with regard to clinical diagnostic evaluations and reports, the licensee be provided with the evaluation report at the same time it is provided to the Board given the potential impact of the findings of the report on a licensee's practice (referring to former section 1361.5(c)(2)(E), which is now 1361.5(c)(1)(A)(vii)).

Suggested Response 2.2 – Staff recommends rejecting this comment, as the Board complies with the provisions of the Information Practices Act, specifically Civil Code section 1798.40, when determining whether and when to release a report that pertains to the physical or psychological condition of the licensee.

Comment 2.3 – CMA asserts that the section addressing worksite monitor requirements and responsibilities is unclear as it implies that the worksite monitor should be practicing in the same specialty as the monitored licensee (referring to former section 1361.5(c)(3)(ii), which is now 1361.5(c)(5)(A)(ii). CMA stated that while this would be appropriate if the worksite monitor is expected to evaluate the quality of care provided, it is not necessary if the monitor is evaluating on non-clinical issues, such as attendance and general sobriety.

Suggested Response 2.3 – Staff recommends accepting this comment, and believes that CMA's concerns have been fully addressed by the proposed rewrite under 1361.5(c)(5)(A)(ii):

> **The worksite monitor's scope of practice shall include the scope of practice of the licensee being monitored, be another licensed health care professional if no monitor with like scope of practice is available, or, as approved by the Board, be a person in a position of authority who is capable of monitoring the licensee at work.**

Comment 2.4 – CMA expressed concern that the provisions dealing with group support meetings may be overly burdensome, because it is unclear if previous participation in a support group would prohibit the licensee from attending a group operated by the same facilitator, since the draft regulation prohibits the licensee and facilitator from having a current or former financial, personal, or business relationship within the last five years (referring to section 1361.5(c)(4)).

Suggested Response 2.4 – Staff recommends accepting this comment, and has redrafted the proposed language under 1361.5(c)(4)(A)(ii)(2) to state:

> **He or she shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. A licensee's previous participation in a group support meeting led by the same facilitator does not constitute a current or former financial, personal, or business relationship.**

Comment 2.5 – CMA and CAFP asked for clarification under Results of Biological Fluid Tests on the time frame in which the cease practice order should be removed if no prohibited substance use exists, including when related public disclosures will be removed, as "immediately" is vague (referring to former section 1361.5(c)(6)(C), which is now 1361.51(d)).

Suggested Response 2.5 – Staff recommends accepting this comment, and believes the issue is resolved under the proposed new language under 1361.51(d), which states: **"If no prohibited substance use exists, the Board shall lift the cease practice order within one (1) business day."**

Comment 2.6 – CMA asked for clarification of what "other substance" would be under

Results of Biological Fluid Tests (referring to former section 1361.5(c)(6)(D), which is now 1361.51(e)).

Suggested Response 2.6 – Staff recommends accepting this comment and has clarified the term "prohibited substance," in the new language under 1361.51(e), which states:

> **For the purposes of this Article, "prohibited substance" means an illegal drug, a lawful drug not prescribed or ordered by an appropriately licensed health care provider for use by the licensee and approved by the Board, alcohol, or other substance the licensee has been instructed by the Board not to use, consume, ingest, or administer to himself or herself.**

The reason it is necessary to include "other substances" is to cover activities that do not fit well within a more narrow definition, such as "huffing," which involves the inhalation of household or industrial chemical products, i.e., paint, glue, gasoline, etc., which can cause intoxication, hallucinations, and other impairment.

Comment 2.7 – CMA and CAPF asked for clarification under Actions by Licensees and Consequences Thereof, where it states that a licensee may not treat a patient while under the influence of drugs or alcohol. They are concerned that proper use of prescribed medication could be lumped into this section as it is worded (referring to former section 1361.5(c)(7)(a)(iii), which is now section 1361.52(a)(3)).

Suggested Response 2.7 – Staff recommends accepting this comment, and believes the issue has been clarified with the proposed new language under 1361.52(a)(3), which states, in pertinent part:

> **(a) A licensee who does any of the following shall be deemed to have committed a major violation of his or her probation:**
>
> **. . .**
>
> **(3) Treats a patient or patients while under the influence of a prohibited substance.**

3. **<u>Comments by Consumers Union Safe Patient Project (CUSPP)</u>**

Comment 3.1 – CUSPP stated that the Board should amend the proposed regulations to include all elements of the Uniform Standards.

Suggested Response 3.1 – Staff recommends rejecting this comment. There are some Uniform Standards that staff deems are not appropriate for the Board to include at this time. For example, most of Uniform Standards #13, and #14 and #15, dealing with private-sector vendors not used by the Board, should not be included. At a later point, if the Board amends the disciplinary guidelines to include monitoring by a vendor, then, at that same time, the Board would have to adopt the Uniform Standards dealing with vendors.

Comment 3.2 – CUSPP stated that the proposed regulation failed to specify the requirement of random drug testing in the first year of probation.

Suggested Response 3.2 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i), and calls for drug testing a minimum of 52-104 times per year. Additionally, subsection (B)(iii) required that the scheduling of biological fluid testing be done on a random basis. Under the new rewrite, these provisions are included under 1361.5(c)(3)(C).

Comment 3.3 – CUSPP stated that the proposed regulation failed to specify that the Board may order a licensee to undergo a drug test at any time.

Suggested Response 3.3 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i). Under the new rewrite, it is included under 1361.5(c)(3)(C).

Comment 3.4 – CUSPP stated that the proposed regulation failed to indicate that nothing precludes the Board from increasing the number of random tests for any reason.

Suggested Response 3.4 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i). Under the new rewrite, these provisions are included under 1361.5(c)(3)(D).

Comment 3.5 – CUSPP stated that the proposed regulation failed to indicate that when the Board finds or has suspicion that a licensee has committed a violation of the testing program or who has committed a major violation, the Board may reestablish the testing cycle, and place the licensee in the most rigorous testing category, in addition to imposing any other disciplinary action that may be pursued.

Suggested Response 3.5 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i), and under (7)(B)(iii). Moreover, pursuant to 1361.5(b) nothing in this section prohibits the Board from imposing additional terms or conditions as warranted. Under the new rewrite, these provisions are included under 1361.52(b)(3) and (4). Among other things, if a licensee uses a prohibited substance, fails to undergo testing when ordered, or attempts to defraud a biological fluid test, the licensee has committed a major violation, and the Board will take action pursuant to 1361.52(b).

Comment 3.6 – CUSPP stated that the proposed regulation failed to include monthly drug testing following five years of successful testing.

Suggested Response 3.6 – Staff recommends rejecting this comment. This provision was specifically included in section 1361.5(c)(5)(B)(i)(1). Under the new rewrite, these provisions are included under 1361.5(c)(3)(C).

Comment 3.7 – CUSPP stated that the proposed regulation failed to identify the exceptions to the testing frequency schedule, including the following: 1) testing parameters for physicians whose

violations did not occur at work, and where drugs/alcohol was a contributing factor; 2) tolling in cases where a licensee is not employed in the healthcare field or has left the state; and 3) testing in cases where no current substance use disorder diagnosis is made.

Suggested Response 3.7 – Staff recommends rejecting this comment. Exceptions to testing frequency were included in section 1361.5(c)(5)(B)(i)(1). Under the new rewrite, these provisions are included under 1361.5(c)(3)(I).

Comment 3.8 – CUSPP stated that the proposed regulation failed to include the process regarding petitions for reinstatement.

Suggested Response 3.8 – Staff recommends accepting this comment, although it is simply a restatement of the Board's authority to accept petitions for reinstatement pursuant to a petition filed under Government Code section 11522. Under the new rewrite, this provision is included under 1361.5(c)(3)(J).

Comment 3.9 – CUSPP stated that the proposed regulation failed to include reporting requirements regarding physicians who tested positive for a banned substance; failed to appear or call in for testing; failed to pay testing costs, and numerous other data requirements.

Suggested Response 3.9 – Staff recommends accepting this comment. Under prior drafts, the reporting requirements were not included since they were directives to the Board, and were not to be included in a licensee's disciplinary order. Under the new rewrite, these provisions are broken out into a separate regulation under 1361.55(e).

Comment 3.10 – CUSPP stated that the proposed regulation does not indicate that failure to complete a board-ordered program is required to be considered a major violation.

Suggested Response 3.10 – Staff recommends rejecting this comment. The Board no longer has a diversion program, and will not be ordering any licensee into any particular type of treatment/monitoring program.

Comment 3.11 – CUSPP stated that the proposed regulation does not indicate that consequences for minor violations include: practice limitations; supervision; increased documentation; and issuance of a citation, fine or warning.

Suggested Response 3.11 – Staff recommends accepting this comment. Under the new rewrite, these provisions are included under 1361.52(d).

Comment 3.12 – CUSPP stated that the proposed regulation does not include criteria that a licensee must meet in order to petition for reinstatement of his or her license.

Suggested Response 3.12 – Staff recommends rejecting this comment. Uniform Standard #12 addresses an "informal" request/petition for reinstatement. The Board does not have an informal process for considering requests/petitions for reinstatement. The licensee must file a petition for reinstatement pursuant to Government Code section 11522. The new rewrite states this requirement under section 1361.5(c)(3)(J).

Comment 3.13 – CUSPP stated that the proposed regulation does not include required timing for a vendor to report major and minor violations, and does not include a list of nine requirements to be met by specimen collectors.

Suggested Response 3.13 – Staff recommends accepting this comment as it relates to specimen collectors only. The Board does not use vendors in other capacities. The new rewrite includes requirements relating to specimen collectors under section 1361.54.

Comment 3.14 – CUSPP stated that the proposed regulation does not include public disclosure requirements related to physicians in diversion programs.

Suggested Response 3.14 – Staff recommends rejecting this comment. The Board does not use a private-sector vendor that provides diversion services, therefore Uniform Standard #14 does not apply at this time, and the regulation should not include it.

Comment 3.15 – CUSPP stated that the proposed regulation does not include audit requirements for private-sector vendors.

Suggested Response 3.15 – Staff recommends rejecting this comment. The Board does not use a private-sector vendor that provides diversion services, therefore Uniform Standard #15 does not apply at this time, and the regulation should not include it.

Comment 3.16 – CUSPP stated that the proposed regulation does not include the public reporting requirements under Uniform Standard #16.

Suggested Response 3.16 – Staff recommends accepting this comment. Under prior drafts, the reporting requirements were not included since they were directives to the Board, and were not to be included in a licensee's disciplinary order. Under the new rewrite, these provisions are broken out into a separate regulation under 1361.55.

4. **Comments by the Wellness Committee of Northern California Psychiatric Society (WCNCPS)**

Comment 4.1 – WCNCPS commented that the term "substance-abusing licensees" is an awkward phrase that implies prejudice against former substance abusers.

Suggested Response 4.1 – Staff recommends rejecting this comment. The term "substance-abusing licensees" is consistent with the language in Business and Professions Code section 315.

Comment 4.2 –WCNCPS stated that imposing "uniform standards" "without deviation" abolishes the individualization of licensees with a history of substance abuse. They further state that not all licensees need the same amount of remedial activities, and that to have the same uniform standards apply to someone who has been in recovery for years as someone just entering recovery does not make sense.

Suggested Response 4.2 – Staff recommends accepting this comment, in part, and has rewritten 1361.5(c) to provide clarification as follows: **"The following probationary terms and conditions, <u>if ordered</u>, shall be used without deviation in the case of a substance-abusing licensee"** (emphasis added). Under Business and Professions Code section 315, the Board's flexibility in how the Uniform Standards are applied are limited, however, not all of the terms and conditions have to be applied in every case. For example, the Board is not required to order every substance-abusing licensee to go to group support meetings, or to have a worksite monitor, but if the Board does order these terms and conditions, the order must comply with the provisions of the 1361.5. Every substance-abusing licensee will have to undergo biological fluid testing, but there are some exceptions to the testing frequency that factor in the licensee's particular situation under 1361.5(c)(3)(I). Additionally, when appropriate, licensees may petition for modification of termination of probation pursuant to Business and Professions Code section 2307.

Comment 4.3 –WCNCPS stated with regard to 1361.5(c)(1) (now section 1361.5(c)(2)) on Notice of Employment Information, that the presiding judge at the hearing usually comments on how extensively one must inform employers and supervisors of the discipline and history of substance abuse. For the Board to require all employers and supervisors to be given personal information and to be possibly contacted by the Board, abolishes discretion between the licensee and the Board's probation officer.

Suggested Response 4.3 – Staff recommends rejecting this comment, as the section on Notice of Employer or Supervisor Information is consistent with the terms of Uniform Standard #3, and provides an important consumer safe guard.

Comment 4.4 –WCNCPS stated with regard to clinical diagnostic evaluations and cease-practice orders (formerly under 1361.5(c)(2)(A and B), now 1361.5(c)(1)), that while the Board should have the right to require a clinical diagnostic evaluation, it should not necessarily order the licensee to cease practicing during the evaluation process. Any order to cease practice should come as a result of the evaluation.

Suggested Response 4.4 – Staff recommends rejecting this comment. The language is consistent with Uniform Standards #1 and #2. The cease-practice order comes into play when the licensee is to be disciplined for unprofessional conduct involving the use of illegal drugs, the abuse of drugs and/or alcohol, or the use of another prohibited substance. A cease-practice order is also imposed if the results of a biological fluid test indicates that a licensee has used a prohibited substance. The use of a cease-practice order under these conditions is an important tool for consumer protection.

Comment 4.5 - WCNCPS stated with regard to worksite monitors (formerly under 1361.5(c)(3)(A), now 1361.5(c)(5)), that the requirements of the worksite monitor are unreasonable and unworkable, and that not many physicians, if any, would agree to take on the task of monitoring. It turns the monitor into a policeman. The extent of the monitor's duties should be individualized case by case.

Suggested Response 4.5 – Staff recommends rejecting this comment. The language is consistent with Uniform Standard #7, and provides for important monitoring of licensees in recovery from alcohol or substance abuse. Moreover, under the new rewrite, the qualifications of a monitor

have been broadened, so that if no monitor with like scope of practice is available, the monitor may be a person in a position of authority who is capable of monitoring the licensee at work, and who is approved by the Board.

Comment 4.6 - WCNCPS stated with regard to support group leaders under 1361.5(c)(4), requiring leaders to report an unexcused absence to the Board within 24 hours would destroy the therapeutic process. They suggested changing the language to require the leader to report "a pattern of disturbing unexcused absences."

Suggested Response 4.6 – Staff recommends rejecting this comment. The language is consistent with Uniform Standard #5, and is an important consumer protection tool to ensure that the licensee is being compliant with the terms of the disciplinary order. The 24-hour reporting requirement for an unexcused absence will allow the probation monitor to check in with the licensee, take action if substance use is suspected, and impose consequences for a violation under 1361.52.

Comment 4.7 - WCNCPS stated with regard to biological fluid testing (formerly under 1361.5(c)(5)(B)(i), now 1361.5(c)(3)(C)), that testing twice per week is unreasonable, is not based on science, and is an undue hardship to the licensee, as these tests are expensive. They contended that testing once a week would suffice, and that testing on Sundays is unreasonable.

Suggested Response 4.7 – Staff recommends rejecting this comment. The language is consistent with Uniform Standard #4, and provides important flexibility with the randomized testing requirement. Some substances can clear from the body within 3 days, so the possibility of being tested twice a week, including on weekends and on holidays, is an important deterrent and consumer-protection safeguard.

Comment 4.8 – WCNCPS objected to the Board issuing a cease-practice order following a positive test (referring to former section 1361.5(c)(6), now 1361.51). They pointed out that false positives are common, and it can take a long time to determine that a positive test is due to actual use. Interrupting the licensee's practice, and notifying employers and supervisors can ruin the licensee's career.

Suggested Response 4.8 – Staff recommends rejecting this comment. The language is consistent with Uniform Standard #8. Moreover, labs are required to provide legally-defensible test results within seven business days pursuant to proposed section 1361.54(a)(6). If the Board confirms that no prohibited substance was used, the cease-practice order must be lifted within one business day pursuant to proposed section 1361.51(d). Moreover, these provisions come into play after the individual has been confirmed to be a substance-abusing licensee. Accordingly, a positive test must be acted upon with consumer protection being paramount.

Comment 4.9 – WCNCPS stated that no mention is made of a requirement that a licensee be tested while on vacation.

Suggested Response 4.9 – Staff recommends accepting this comment, and the requirement that a licensee be tested while on vacation is included in the new rewrite under 1361.5(c)(3)(G).

5. **Comments by the California Hospital Association (CHA)**

Comment 5.1 –CHA recommended that the regulation be amended to require notice be provided to the licensee's employer and any medical staff(s) to which the licensee is a member with clinical privileges.

Suggested Response 5.1 – Staff recommends accepting this comment. Under 1361.5(c)(2), the new rewrite includes the Chief of Staff and the Health or Well Being Committee Chair, or equivalent, under the definition of "supervisors," when the licensee has medical staff privileges.

Comment 5.2 – CHA recommended that the regulation be amended to require direct notice by the licensee to their employers, supervisors, Chiefs of Staff, and Well Being Committee Chairs, as applicable, instead of simply relaying contact information and a consent form to the Board.

Suggested Response 5.2 – Staff recommends rejecting this comment. The current draft language is consistent with Uniform Standard #3. The Board may require the licensee to directly notify his or her employers under the disciplinary guidelines. The purpose of this uniform standard is to obtain specific consent from the licensee to permit the Board and the licensee's employers, supervisors, etc., to be in communication with each other as needed to promote public protection and the rehabilitation of the licensee.

Comment 5.3 – CHA recommended that the regulation be amended to exempt the monitored licensee from the medical staffs' hearing rights, and include certain protections from liability against the hospital and its medical staff whenever concurrent restrictions are imposed on a monitored licensee who is also a member of a hospital's medical staff with privileges.

Suggested Response 5.3 – Staff recommends rejecting this comment. Hearing rights are governed by separate statutes, including Business and Professions Code sections 809.2 and 809.3, and cannot be changed by the proposed regulations.

6. **Joint Comments by the California Public Protection and Physician Health (CPPPH), California Society of Addiction Medicine (CSAM), California Hospital Association (CHA), and California Psychiatric Association (CPA)**

Comment 6.1 – CPPPH, CSAM, CHA, and CPA jointly recommended that the regulation be amended to require notice be provided to the licensee's employer and any medical staff(s) to which the licensee is a member with clinical privileges.

Suggested Response 6.1 – Staff recommends accepting this comment. Under 1361.5(c)(2), the new rewrite includes the Chief of Staff and the Health or Well Being Committee Chair, or equivalent, under the definition of "supervisors," when the licensee has medical staff privileges.

Comment 6.2 – CPPPH, CSAM, CHA, and CPA jointly recommended that the regulation be amended to require direct notice by the licensee to their employers, supervisors, Chiefs of Staff, and Well Being Committee Chairs, as applicable, instead of simply relaying contact information and a consent form to the Board.

Suggested Response 6.2 – Staff recommends rejecting this comment. The current draft language is consistent with Uniform Standard #3. The Board may require the licensee to directly notify his or her employers under the disciplinary guidelines. The purpose of this uniform standard is to obtain specific consent from the licensee to permit the Board and the licensee's employers, supervisors, etc., to be in communication with each other as needed to promote public protection and the rehabilitation of the licensee.

Comment 6.3 – CPPPH, CSAM, CHA, and CPA jointly pointed out that the Board can order a licensee who is required to undergo a clinical diagnostic evaluation to cease practice and be randomly drug tested at least twice a week while awaiting the results. Further, while the evaluator is required to submit a full written report no later than 10 days from being assigned the evaluation (or within 30 days, if an extension is granted), there is no requirement for review and determination by the Board within a specified time. They stated that such a burden should not be placed on the licensee without a specific rule governing the length of time before it would be either continued for cause or lifted. They recommended a time frame of five business days for Board review and determination.

Suggested Response 6.3 – Staff recommends accepting this comment, and has incorporated a time frame for the Board to review the clinical evaluation report under 1361.5(c)(1)(D) as follows: "**The Board shall review the clinical diagnostic evaluation report within five (5) business days of receipt to determine whether the licensee is safe to return to either part-time or full-time practice…"**

Comment 6.4 – CPPPH, CSAM, CHA, and CPA jointly contended that the requirements for a worksite monitor may make it inordinately difficult for the licensee to find a qualified individual to fill the role. Without someone to fill the role, a licensee who is deemed safe to practice, will not be permitted to practice.

Suggested Response 6.4 - Staff recommends accepting this comment, and has drafted amended language under 1361.5(c)(5)(A)(ii):

> **The worksite monitor's scope of practice shall include the scope of practice of the licensee being monitored, be another licensed health care professional if no monitor with like scope of practice is available, or, as approved by the Board, be a person in a position of authority who is capable of monitoring the licensee at work.**

Comment 6.5 – CPPPH, CSAM, CHA, and CPA jointly opposed the requirement that "the worksite monitor shall verbally report any *suspected* (emphasis added) substance abuse to the Board and the licensee's employer within one business day of occurrence." They believe that suspected substance abuse should not be reported, and instead, the monitor should be able to require the licensee to submit to a biological fluid test within four hours.

Suggested Response to 6.5 – Staff recommends rejecting this comment. The current draft language is consistent with Uniform Standard #7, and provides important information to the Board and the licensee's employers and supervisors, so that any necessary safeguards can be put in place while awaiting a legally defensible biological fluid test.

Comment 6.6 – CPPPH, CSAM, CHA, and CPA jointly stated that a cease-practice order should only be imposed once there is confirmation of a legally-defensible report from the testing entity indicating that the licensee has used a prohibited substance, and the Board should not take such action upon initial receipt of a positive test.

Suggested Response to 6.6 – Staff recommends rejecting this comment. The current draft language is consistent with Uniform Standard #8, and it is imperative for consumer protection for the Board to be able to issue a cease-practice order immediately upon receiving a positive test result for a licensee who has had a history of alcohol or substance abuse.

Comment 6.7 – CPPPH, CSAM, CHA, and CPA jointly expressed concern with the section that says, "if no prohibited substance use exists, the Board shall immediately lift the cease-practice order," because the term "immediately" is not defined.

Suggested Response 6.7 – Staff recommends accepting this comment, and believes the issue is resolved under the proposed new language under 1361.51(d), which states: **"If no prohibited substance use exists, the Board shall lift the cease-practice order within one (1) business day."**

Comment 6.7 – CPPPH, CSAM, CHA, and CPA jointly expressed concern regarding former section 1361.5(c)(8)(A) (now section 1361.53(a)(3)) as it requires the licensee to have negative biological fluid testing reports for at least six months and two positive worksite monitor reports before he or she is eligible to return to full or partial practice. They stated that temporarily closing a practice for longer than three months may result in permanent closure, poor continuity of patient care, and loss of medical skills. They argued that return to practice should be based on an assessment by a licensed healthcare practitioner and not on arbitrary durations. They also pointed out that physicians seeking to return to work should not be required to produce a worksite monitor report if they have not been working, as they would not have such a report.

Suggested Response 6.7 – Staff recommends rejecting the comment, in part, regarding the objection to the requirement for six months of negative testing before a licensee is authorized to return to full or part-time practice. This requirement is consistent with Uniform Standard #11, and is an important consumer-protection provision.

Staff recommends accepting the comment with regard to worksite monitor reports, and has amended the language under the rewrite to require: **"…two (2) positive worksite monitor reports (if currently being monitored)…"**

7. **<u>Comments by the California Psychiatric Association (CPA)</u>**

Comment 7.1 – CPA pointed out the limitations of SB 1441 in addressing substance-abusing licensees with co-occurring mental disorders. They pointed out that if both the substance-abuse issue and the mental disorder are not addressed concurrently and in an integrated fashion, then the treatment prognosis for the licensee is diminished and the goals are undermined. They stated that guidelines and standards for co-occurring mental disorders need to be developed and adopted.

Proposed Response 7.1 – Staff recommends rejecting this comment, as the proposed regulations do not impair concurrent treatment for co-occurring mental disorders. The Board continues to have authority to order a psychiatric evaluation and require psychotherapy when necessary.

Comment 7.2 – CPA pointed out that Article 2, starting at section 1357 contains regulations relating to the Impaired Physician Diversion Program, which no longer exists, and suggested that they be repealed.

Proposed Response 7.2 – While this comment is not directed to the current proposed regulation, staff agrees that the regulations relating to the Impaired Physician Diversion Program should be repealed, and that will occur via a different regulatory package.

Comment 7.3 – CPA contended that the regulations to implement SB 1441 authorize the Board to issue orders against licensees to restrict, suspend or cease practice, but do not provide the affected licensee with any right to notice or hearing prior to requiring of restriction or cessation of practice.

Proposed Response 7.3 – Staff recommends rejecting this comment, as the proposed regulations come into play if the licensee is to be disciplined for unprofessional conduct involving the use of drugs, alcohol, or another prohibited substance, and occurs after a full administrative hearing or upon stipulation. The emergency cease-practice orders required by these regulations, such as when a licensee tests positive for a prohibited substance while on probation, are necessary for public protection, and also have a time limitation for the Board to confirm results. Finally, a licensee continues to have the right to file a writ with a Superior Court for review of the Board's decision.

8. **Comments by Julianne D'Angelo Fellmeth, Administrative Director for the Center for Public Interest Law (Ms. Fellmeth's written comments were reiterated, in part, at the hearing)**

Comment 8.1 – Ms. D'Angelo Fellmeth pointed out that some language was missing under 1361.5(c)(5) that is provided for under Uniform Standard #4, namely: "Thereafter [i.e., after the second year of probation (sic)], administration of one (1) time per month if there have been no positive drug tests in the previous five (5) consecutive years of probation or diversion. Nothing precludes a board from increasing the number of random tests for any reason. Any board who finds or has suspicion that a licensee has committed a violation of the board's testing program or who has committed a Major violation, as identified in Uniform Standard 10, may reestablish the testing cycle by placing that licensee at the beginning of level 1, in addition to any other disciplinary action that may be pursued."

Proposed Response 8.1 – Staff recommends accepting this comment, in part, and has amended the language now under 1361.5(c)(3), regarding biological fluid testing to include the testing schedule provided for under Uniform Standard #4, and to clarify that the Board may increase the number of random tests for any reason. Further, under section 1361.52 of the new rewrite, the proposed language indicates that if the licensee has committed a major violation, the Board will take action, and may, among other things, increase the frequency of biological fluid testing, and refer the licensee for further disciplinary action.

Comment 8.2 – Ms. D'Angelo Fellmeth commented that some of the exceptions to the testing frequency schedule Uniform Standard #4 were not included in the proposed regulation, specifically regarding previous testing/sobriety, violations outside of employment, tolling, and testing for licensees not employed in a healthcare field. She stated that these provisions should be included.

Proposed Response 8.2 – Staff recommends accepting this comment, and has amended the language to include all of the exceptions to the testing frequency schedule under 1361.5(c)(3)(I).

Comment 8.3 – Ms. D'Angelo Fellmeth commented that several sections toward the end of Uniform Standard #4, namely "Petitions for Reinstatement," "Outcomes and Amendments," "Historical Data – Two Years Prior to Implementation of Standard," "Post Implementation Data – Three Years," and "Data Collection" were not included in the draft regulation, but should be.

Proposed Response 8.3 – Staff recommends accepting this comment and has amended the language to include all of these provisions from Uniform Standard #4. The section on Petitions for Reinstatement is included under 1361.5(c)(3)(J), and the reporting requirements have been placed in a separate proposed section, 1361.55(e).

Comment 8.4 – Ms. D'Angelo Fellmeth commented that 1361.5(c)(4) relating to group support meetings authorizes the Board to order a licensee to go to group meetings following such recommendation by the evaluator, however Uniform Standard #5 does not contain that limitation. She says that a board may order a licensee to attend group meetings even if that has not been recommended by an evaluator, and that the limitation should be removed.

Proposed Response 8.4 – Staff recommends accepting this comment, and has amended the language to read, "If the Board requires a licensee to participate in group support meetings, the following shall apply:…"

Comment 8.5 – Ms. D'Angelo Fellmeth commented that provisions under Uniform Standard #6 used in determining whether inpatient/outpatient or other type of treatment is necessary were not included in the draft regulations, but should be.

Proposed Response 8.5 – Staff recommends accepting this comment, in part, and has amended the language to include the provisions under 1361.5(c)(1)(A)(v) to be factored into the clinical evaluator's recommendations. The Board will not be ordering licensees into a specific type of program, but the clinical evaluator will make treatment recommendations based on the provisions of Uniform Standard #6.

Comment 8.6 – Ms. D'Angelo Fellmeth pointed out there is a discrepancy between the provisions of Uniform Standard #7 and the draft regulation under 1361.5(c)(3) with regard to how and when a worksite monitor reports suspected substance abuse.

Proposed Response 8.6 – Staff recommends accepting this comment, and has made a proposed amendment to the language under 1361.5(c)(5)(C)(i) to read as follows:

> **The worksite monitor shall verbally report any suspected substance abuse to the Board and the licensee's employer or supervisor as defined in subsection**

(c)(2) within one (1) business day of occurrence. If the suspected substance abuse does not occur during the Board's normal business hours, the verbal report shall be made to the Board within one (1) hour of the next business day. A written report that includes the date, time, and location of the suspected abuse, the licensee's actions and any other information deemed important by the worksite monitor shall be submitted to the Board within 48 hours, or by the next business day, of the occurrence.

Comment 8.7 – Ms. D'Angelo Fellmeth stated that the draft regulations did not include all of the provisions of Uniform Standard #10 regarding major violations, and specifically did not include "failure to complete a board-ordered program" as a major violation. She proposed that since the Board may determine that the phrase is referring to a diversion program, which the Board no longer has, then the Board should consider including the failure to complete the probationary terms and conditions as a major violation.

Proposed Response 8.7 – Staff recommends accepting this comment, in part. The Board will not order the licensee into any particular treatment program. Staff, however, has amended the language under 1361.52(a)(8) to include the failure "to comply with any term or condition of his or her probation that impairs public safety," as a major violation. The limitation that it has to impair public safety is an important distinction from what qualifies as a minor violation.

Comment 8.8 – Ms. D'Angelo Fellmeth stated that the consequences for a major violation under Uniform Standard #10 are not discretionary, but the draft regulation has made implementation of the consequences discretionary by the use of "may." She contended that if a licensee commits a major violation, the Board is required to issue a cease practice order, **and** order the licensee to undergo a new clinical diagnostic evaluation, **and** require the licensee to test negative for at least a month of continuous testing before being allowed to go back to work.

Proposed Response 8.8 – Staff recommends accepting this comment, in part, and has amended the language under 1361.52(b) to include the following language: **"If a licensee commits a major violation, the Board will take one or more of the following actions:…"**

While staff agrees that action is required when a licensee commits a major violation, the Board retains discretion on what consequences to impose. Not all major violations are created equal. For example, committing multiple minor violations, which may include missing group support meetings, is considered a major violation along with treating patients while under the influence of a prohibited substance. A cease practice order and referral for revocation may not be warranted under the first example, but would be warranted under the second.

Comment 8.9 – Ms. D'Angelo Fellmeth stated that Uniform Standard #10 contains seven consequences that appear to be mandatory, but the proposed regulation only includes three of those seven, and does not make the consequences mandatory.

Proposed Response 8.9 – Staff recommends accepting this comment, in part, and has amended the language under 1361.52(c) to include the seven consequences contained in Uniform Standard #10 for a minor violation. Additionally, the language has been amended to state: **"If a licensee commits a minor violation, the Board will take one or more of the following actions:…"**

Staff disagrees that all of the consequences for a minor violation are mandatory, and the Board retains discretion on what consequences to impose.

Comment 8.10 – Ms. D'Angelo Fellmeth stated that the Board should include Uniform Standard #12, regarding an informal petition for reinstatement, in its proposed regulation.

Proposed Response 8.10 – Staff recommends rejecting this comment. The Board does not have a mechanism for considering informal petitions for reinstatement. An individual whose license has been revoked can petition for reinstatement under Government Code section 11522, and will be required to show clear and convincing evidence of rehabilitation. These petitions are decided by an administrative law judge and are subject to Board approval.

Comment 8.11 – Ms. D'Angelo Fellmeth pointed out that the proposed regulation does not contain Uniform Standards #13, #14, and #15, which contain standards pertaining to boards that contract with an outside vendor to operate a diversion program. While she acknowledged that the Board does not contract with vendors to operate a diversion program, she stated that Uniform Standard #13 contains some important standards for specimen collectors, and she encouraged the Board to include those standards.

Proposed Response 8.11 – Staff recommends accepting the comment to the extent it asks that the standards for specimen collectors be included. Staff has drafted a new section, 1361.54 - Requirements for Laboratories/Testing Locations and Specimen Collectors for Testing Substance-Abusing Licensees, and has included the requirements from Uniform Standard #4 and #13, dealing with laboratories/testing locations and specimen collectors.

Because Uniform Standards #14 and #15 deal with private-sector vendors not used by the Board, staff has determined that they should not be included in these regulations. At a later point, if the Board amends the disciplinary guidelines to include monitoring by a vendor, then, at that same time, the Board would have to adopt the Uniform Standards dealing with vendors.

Comment 8.12 – Ms. D'Angelo Fellmeth states that Uniform Standard #16, which addresses mandatory reporting by the Board to DCA and the Legislature regarding a number of factors relating to substance-abusing licensees, is not included in the proposed regulation, and should be.

Proposed Response 8.12 – Staff recommends accepting this comment, and has drafted a new section, 1361.55 – Reporting Requirements Relating to Substance-Abusing Licensees, that is consistent with Uniform Standard #16.

9. **Comments by Michelle Monserrat Ramos, Consumers Union, California Safe Patient Network Made at the October 25, 2013 Hearing**

Comment 9.1 – Ms. Monserrat Ramos asked that the Board implement the full Uniform Standards as SB 1441 requires. She says she cannot believe how long it is taking to implement the Uniform Standards. She wants to remind the Board that patients have died due to substance-abusing physicians. She reiterated the written comments received from Consumers Union regarding provisions not included in the draft regulation.

Proposed Response 9.1 – Staff recommends accepting this comment, in part. Staff has made substantial changes to the proposed regulation in the rewrite so that the language is more consistent with SB 1441 where appropriate. Moreover, the reporting requirements from Uniform Standards #4 and #16 are now included in a separate regulatory section, 1361.55, as a directive to the Board.

Staff recommends rejecting this comment to the extent that it calls for the inclusion of all provisions of the Uniform Standards in the proposed regulations. There are some Uniform Standards that staff deems are not appropriate for the Board to include at this time. For example, most of Uniform Standards #13, and #14 and #15, dealing with private-sector vendors not used by the Board, should not be included. If the Board amends the disciplinary guidelines to include monitoring by a vendor in the future, then, at that same time, the Board would have to adopt the Uniform Standards dealing with vendors.

TITLE 16 MEDICAL BOARD OF CALIFORNIA

NOTICE IS HEREBY GIVEN that the Medical Board of California is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at Embassy Suites San Francisco Airport - Waterfront,150 Anza Blvd, Burlingame, CA 94010, at 9:00 a.m., on February 7, 2014. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Medical Board of California at its office not later than 5:00 p.m. on January 27, 2014, or must be received by the Medical Board of California at the hearing. The Medical Board of California, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 2018, 3502, and 3510 of the Business and Professions Code, and to implement, interpret or make specific Sections 2058, 3502, and 3502.1 of said Code, the Medical Board of California is considering changes to Division 13.8 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST

A. Informative Digest

The Board is proposing the following changes:

Amend Section 1399.541 in Article 4 of Division 13.8.

The existing regulation permits a physician assistant (PA) to act as a first or second assistant in surgery under the supervision of an approved supervising physician.

This proposal would permit a PA to act as a first or second assistant in surgery without the personal presence of the supervising physician if the supervising physician is immediately available to the PA. “Immediately available” means able to return to the patient, without delay, upon the request of the PA or to address any situation requiring the supervising physician’s services.

This proposal would also delete the word, “approved” as a modifier to the supervising physician. Senate Bill 1981 (Stats. 1998, Chapter 736) repealed Business and Professions Code Section 3515. SB 1981 deleted the requirement that the Board review and approve applications for PA supervisors.

B. Policy Statement Overview/Anticipated Benefits of Proposal

The Board's highest priority is the protection of the public and the proposed regulations will provide protection of the people of California by updating and clarifying supervision requirements while a PA acts as a first or second assistant in surgery. This regulatory proposal benefits the health and welfare of California residents because it represents the current standard of practice within the medical community, and will enhance consumer protection by allowing better access to care while still protecting the consumer. This proposal would permit the physician to address other patient needs while authorized PA services are being performed. Under this proposal the physician is still responsible for supervising the PA and is required to be "immediately available" to the PA, if needed, at the request of the PA or to address any situation requiring the supervising physician's services.

C. Consistency and Compatibility with Existing State Regulations

After conducting a review for similar regulations, the Board has found that these are the only regulations concerning this subject area. Therefore, the Board has determined that the proposed regulatory changes are neither inconsistent nor incompatible with existing regulations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Sections 17500 - 17630 Require Reimbursement: None.

Business Impact

The Medical Board of California has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts or evidence/documents/testimony:

The Medical Board regulates physicians and surgeons in the State of California, and the Physician Assistant Board, within the jurisdiction of the Medical Board, regulates PAs. The Medical Board currently has approximately 128,641 licensees and the Physician Assistant Board has

approximately 9,101 licensees for FY 2012-2013. PAs work in a variety of practice settings and specialties under the supervision of licensed physicians. The boards do not have data on either the number of physicians who supervise PAs by practice setting or the number of PAs who work as first or second assistants in surgery.

This regulation will clarify supervision requirements for PAs and supervising physicians as to the availability of the supervising physician when PAs are acting as first or second assistants in surgery. However, according to comments received at public board meetings, this proposed regulatory change represents the current evolution of the standard of practice within the medical community and, therefore, it is the Medical Board's understanding that this proposal would not have an adverse economic impact on the physicians or PAs who would be subjected to this requirement.

Cost Impact on Representative Private Person or Business

The Medical Board of California is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs None

EFFECT ON SMALL BUSINESS

The Medical Board of California has determined that the proposed regulations or would not affect small businesses. The Board does not license businesses, the Board licenses individuals; therefore, there is no impact on small businesses or any business.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Impact on Jobs/Businesses

The Medical Board of California has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses, the elimination of jobs or existing businesses, or the expansion of businesses in the State of California.

Benefits of Regulation

The Medical Board of California has determined that this regulatory proposal will have the following benefits to health and welfare of California residents, worker safety, and the state's environment:

This proposal will update and clarify supervision requirements while a PA acts as a first or second assistant in surgery. Consumer protection is enhanced because physician supervision of PAs acting as first or second

assistants in surgery is precisely defined. This regulatory proposal benefits the health and welfare of California residents because it

represents the current standard of practice within the medical community and will enhance consumer protection by allowing better access to care while still protecting the consumer. This proposal would permit the physician to address other patient needs while authorized PA services are being performed. Under this proposal the physician is still responsible for supervising the PA and is required to be "immediately available" to the PA if needed at the request of the PA or to address any situation requiring the supervising physician's services.

CONSIDERATION OF ALTERNATIVES

The Medical Board of California must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Medical Board of California has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, any document incorporated by reference, the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request to the contact person named below, or by accessing the Board's or the PA Board's website.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the websites listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Glenn L. Mitchell, Jr., Executive Officer Physician Assistant Board
Address:	2005 Evergreen Street, Suite 1100 Sacramento, CA 95815
Telephone No.:	916.561.8783
Fax No.:	916.263.2671
E-Mail Address:	glenn.mitchell@mbc.ca.gov

The backup contact person is:

Name:	Christine Valine Medical Board of California
Address:	2005 Evergreen Street, Suite 1200 Sacramento, CA 95815
Telephone No.:	916.263.2389
Fax No.:	916.263.2387
E-Mail Address:	regulations@mbc.ca.gov

Website Access: Materials regarding this proposal can be found at:

www.pac.ca.gov

or:

www.mbc.ca.gov

MEDICAL BOARD OF CALIFORNIA
INITIAL STATEMENT OF REASONS

Hearing Date: 7 February 2014

Subject Matter of Proposed Regulations: Supervision requirements: Physician Assistants acting as first for second assistants in surgery

Section Affected: 1399.541

Specific purpose of each adoption, amendment, or repeal

Problem being addressed

Physician Assistants (PA) are licensed health care practitioners that perform authorized medical services under the supervision of a licensed physician and surgeon (Business and Professions Code section 3502). Business and Professions Code section 3510 authorizes the Medical Board of California ("Medical Board") to amend or adopt regulations under its jurisdiction, including regulations regarding the scope of practice for PAs. The Physician Assistant Board, a board within the jurisdiction of the Medical Board, is authorized to make recommendations to the Medical Board concerning the scope of practice for PAs (Business and Professions Code section 3509).

Existing law permits a PA to act as first or second assistant in surgery under the supervision of an approved supervising physician. In 2011, a concern was raised by a PA licensee to the Physician Assistant Board, that the current regulation at Section 1399.541 did not reflect current medical community standards when a PA acts as a first or second assistant in surgery. Additionally, the regulation was unclear regarding the degree of physician supervision of a PA acting as a first or second assistant in surgery.

Finally, the term, "approved supervising" physician as referenced in the current version of Section 1399.541(i)(2) needs to be removed as it is no longer accurate; legislation in 2002 eliminated the requirement that physicians who wish to supervise PAs be "approved" by the Medical Board of California. (Senate Bill 1981 (Stats. 1998, Chapter 736) repealed Business and Professions Code Section 3515.) After public discussion and deliberation, the PA Board relayed these concerns and a recommend proposal to the Medical Board for possible action.

To address the foregoing issues, the Medical Board proposes to amend Section 1399.541 to permit authorized medical services without the personal presence of the supervising physician if the supervising physician is immediately available to the PA. "Immediately available" would be defined as able to return to the patient, without delay, upon the request of the PA or to address any situation requiring the supervising physician's services.

Anticipated benefits from this regulatory action

This proposal will amend the current regulation to update and clarify supervision requirements while a PA acts as a first or second assistant in surgery.

Consumer protection is assured because the term, “immediately available” is precisely defined and will ensure that the PA is appropriately supervised when acting as a first or second assistant in surgery. Additionally, amending the regulation will not reduce consumer protection because the supervising physician will be immediately available to provide assistance to the PA.

Factual Basis/Rationale

Under the existing regulation, a PA may act as a first or second assistant in surgery under the supervision of a supervising physician. To reflect current medical community standards, the proposal would clarify that a PA may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the PA. “Immediately available” would be defined as able to return to the patient without delay, upon the request of the PA or to address any situation requiring the supervising physician’s services.

Over the course of numerous meetings from 2011 to 2013 for the Medical Board, Physician Assistant Board and Physician Assistant Committee, participants discussed the need to update the regulation and to specify the degree of supervision required for a PA when acting as a first or second assistant in surgery in light of the evolution of current medical practices for both professions.

Discussion originally focused on a legal opinion rendered in 2005 which interpreted Section 1399.541 to prohibit a PA from opening and closing surgical procedures on a patient under general anesthesia without the personal presence of a supervising physician and surgeon. However, at Physician Assistant Board and Committee meetings it was noted that the regulations have not been changed since 1991 and the 2005 legal interpretation was not consistent with the evolution of the practice. Conscious sedation did not exist when the regulations were first adopted. Further, the use of a PA in surgery has increased since 1991 and it was felt that PAs have proved to be capable of performing the requested procedures safely. Clarifying that the physician supervision would entail making the physician “immediately available” allows better access to care and still protects the consumer as the physician is still required to be “immediately available” to the PA and the patient. This proposal would allow the surgeon to leave the operating room to dictate the case, make phone calls, meet the next patient in surgery pre-op, and still make the physician immediately available to return to the operating room if needed. It was suggested that many surgery centers already operate in this manner when the physician is comfortable with the surgery team. Consequently, it was recommended to the Medical Board that the current regulation be amended to update it consistent with current practice.

A prior draft regulation to amend section 1399.541 was submitted to the Medical Board of California in May 2012, but the Medical Board had concerns about the breadth of the regulation and declined to take action. After considering the Medical Board's concerns, Physician Assistant Board staff started over and developed a different regulatory proposal.

In late July 2013, the Physician Assistant Board staff shared the new draft language with Medical Board of California staff and legal counsel to anticipate any concerns the Medical Board of California members may have. None were identified. At the August 2013 Physician Assistant Board meeting, board members voted to approve the proposed language and submit the proposal to the Medical Board of California for its consideration.

At their October 24, 2013 meeting, members of the Medical Board of California considered the proposed regulatory change and voted to direct staff to begin the rulemaking process to adopt the proposed regulatory changes.

At the meeting it was noted that the proposed language, which includes the term, "immediately available," is similar to Title 16, California Code of Regulations Section 1364.50 for physician supervision of other mid-level practitioners. Thus, with this proposal, the term, "immediately available" will be standardized, familiar, and understood by supervising physicians and PAs. This will eliminate PA and supervising physician confusion as to the definition of "immediately available."

This proposal would also make a non-substantive change to the text to strike the word "approved" as a modifier to the supervising physician to eliminate an inaccurate and outdated reference to past statutory requirements. Senate Bill 1981 (Stats. 1998, Chapter 736) repealed Business and Professions Code Section 3515. SB 1981 deleted the requirement that the Board review and approve applications for PA supervisors. Business and Professions Code Section 3515 was repealed by its own terms on January 1, 2002.

Underlying Data

Technical, theoretical or empirical studies, reports, or documents relied upon (if any):

1. Legal Opinion to Richard Wallinder, Executive Officer of the Physician Assistant Committee, dated April 25, 2005.

2. Meeting Minutes from the Physician Assistant Committee Meeting held May 19, 2011.

3. Meeting Minutes from Physician Assistant Committee Meeting held February 6, 2012.

4. Relevant Meeting Minutes from the Medical Board of California Meeting held May 3-4, 2012.

5. Meeting Minutes from Physician Assistant Committee Meeting held May 7, 2012.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the following facts or evidence/documents/testimony:

The Medical Board regulates physicians and surgeons in the State of California and the Physician Assistant Board, within the jurisdiction of the Medical Board, regulates PAs. The Medical Board currently has approximately 128,641 licensees and the Physician Assistant Board has approximately 9,101 licensees for FY 2012-2013. PAs work in a variety of practice settings and specialties under the supervision of licensed physicians. The boards do not have data on either the number of physicians who supervise PAs by practice setting or the number of PAs who work as first or second assistants in surgery.

This regulation will clarify supervision requirements for PAs and supervising physicians as to the availability of the supervising physician when PAs are acting as first or second assistants in surgery. However, according to public comments received at board meetings, this proposed regulatory change represents the current evolution of the standard of practice within the medical community and, therefore, it is the Medical Board's understanding that this proposal would not have an adverse economic impact on the physicians or PAs who would be subjected to this requirement.

Economic Impact Assessment

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because this proposed regulation represents the current evolution of the standard of practice within the medical community and will merely make conforming changes consistent with that practice by adding the term "immediately available" and an associated definition. As such, this proposal would not create or eliminate jobs within California.

- It will not create new business or eliminate existing businesses within the State of California because this proposed regulation represents the current standard of practice within the medical community, and will add the term, 'immediately available" and, as such, would not create new business or eliminate existing businesses in California.

- It will not affect the expansion of businesses currently doing business within the State of California because this proposed regulation represents the current standard of practice within the medical community, and will merely make conforming changes consistent with that practice by adding the term, "immediately available" and, an associated definition. As such, this proposal would not affect the expansion of businesses currently doing business within California.

- This regulatory proposal benefits the health and welfare of California residents by allowing better access to care while protecting the consumer, as the physician is required to be “immediately available” to the PA and the patient.

- This regulatory proposal does not affect worker safety because this proposed regulation represents current standard of practice within the medical community and will add the term “immediately available.” It should not affect worker safety, as the physician is still responsible for supervising and making himself or herself “immediately available” to the PA and the patient.

- This regulatory proposal does not affect the state’s environment because the regulation reflects the current standard of practice within the medical community and seeks to clarify supervision requirements while a PA acts as a first or second assistant in surgery.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

1) Not adopt the regulation. This alternative was rejected because the current regulation does not reflect the current medical community standards and does not define or specify the degree of supervision required for a PA acting as a first or second assistant in surgery.

2) Adopt the regulation. Although alternative regulatory language was considered in 2012, the Medical Board determined that this alternative was the most feasible because it will ensure that the regulations reflect the current medical community standards with regard to PAs acting as first or second assistants in surgery, as well as adding and defining the term, “immediately available.” This language will eliminate PA and supervising physician confusion with regard to the degree of physician supervision required for safe practice.

MEDICAL BOARD OF CALIFORNIA
SPECIFIC LANGUAGE OF PROPOSED CHANGES
MEDICAL SERVICES PEFORMABLE

Amend Section 1399.541 of Article 4 of Division 13.8 as follows:

§ 1399.541. Medical Services Performable.

Because physician assistant practice is directed by a supervising physician, and a physician assistant acts as an agent for that physician, the orders given and tasks performed by a physician assistant shall be considered the same as if they had been given and performed by the supervising physician. Unless otherwise specified in these regulations or in the delegation or protocols, these orders may be initiated without the prior patient specific order of the supervising physician.

In any setting, including for example, any licensed health facility, out-patient settings, patients' residences, residential facilities, and hospices, as applicable, a physician assistant may, pursuant to a delegation and protocols where present:

(a) Take a patient history; perform a physical examination and make an assessment and diagnosis therefrom; initiate, review and revise treatment and therapy plans including plans for those services described in Section 1399.541(b) through Section 1399.541(i) inclusive; and record and present pertinent data in a manner meaningful to the physician.

(b) Order or transmit an order for x-ray, other studies, therapeutic diets, physical therapy, occupational therapy, respiratory therapy, and nursing services.

(c) Order, transmit an order for, perform, or assist in the performance of laboratory procedures, screening procedures and therapeutic procedures.

(d) Recognize and evaluate situations which call for immediate attention of a physician and institute, when necessary, treatment procedures essential for the life of the patient.

(e) Instruct and counsel patients regarding matters pertaining to their physical and mental health. Counseling may include topics such as medications, diets, social habits, family planning, normal growth and development, aging, and understanding of and long-term management of their diseases.

(f) Initiate arrangements for admissions, complete forms and charts pertinent to the patient's medical record, and provide services to patients requiring continuing care, including patients at home.

(g) Initiate and facilitate the referral of patients to the appropriate health facilities, agencies, and resources of the community.

(h) Administer or provide medication to a patient, or issue or transmit drug orders orally or in writing in accordance with the provisions of subdivisions (a)-(f), inclusive, of Section 3502.1 of the Code.

(i)(1) Perform surgical procedures without the personal presence of the supervising physician which are customarily performed under local anesthesia. Prior to delegating any such surgical procedures, the supervising physician shall review documentation which indicates that the physician assistant is trained to perform the surgical procedures. All other surgical procedures requiring other forms of anesthesia may be performed by a physician assistant only in the personal presence of a~~n approved~~ supervising physician.

(2) A physician assistant may also act as first or second assistant in surgery under the supervision of a~~n approved~~ supervising physician. The physician assistant may so act without the personal presence of the supervising physician if the supervising physician is immediately available to the physician assistant. "Immediately available" means able to return to the patient, without delay, upon the request of the physician assistant or to address any situation requiring the supervising physician's services.

Note: Authority cited: Sections 2018, 3502 and 3510, Business and Professions Code. Reference: Sections 2058, 3502 and 3502.1, Business and Professions Code.

West's Annotated California Codes
Business and Professions Code (Refs & Annos)
Division 2. Healing Arts (Refs & Annos)
Chapter 1. General Provisions (Refs & Annos)
Article 6. Unearned Rebates, Refunds and Discounts (Refs & Annos)

West's Ann.Cal.Bus. & Prof.Code § 655

§ 655. Prohibited arrangements between optometrists and registered dispensing opticians or suppliers of optometric appliances or devices

Currentness

(a) No person licensed under Chapter 7 (commencing with Section 3000) of this division may have any membership, proprietary interest, coownership, landlord-tenant relationship, or any profit-sharing arrangement in any form, directly or indirectly, with any person licensed under Chapter 5.5 (commencing with Section 2550) of this division.

(b) No person licensed under Chapter 5.5 (commencing with Section 2550) of this division may have any membership, proprietary interest, coownership, landlord-tenant relationship, or any profit sharing arrangement in any form directly or indirectly with any person licensed under Chapter 7 (commencing with Section 3000) of this division.

(c) No person licensed under Chapter 7 (commencing with Section 3000) of this division may have any membership, proprietary interest, coownership, landlord-tenant relationship, or any profit-sharing arrangement in any form, directly or indirectly, either by stock ownership, interlocking directors, trusteeship, mortgage, trust deed, or otherwise with any person who is engaged in the manufacture, sale, or distribution to physicians and surgeons, optometrists, or dispensing opticians of lenses, frames, optical supplies, optometric appliances or devices or kindred products.

Any violation of this section constitutes a misdemeanor as to such person licensed under Chapter 7 (commencing with Section 3000) of this division and as to any and all persons, whether or not so licensed under this division, who participate with such licensed person in a violation of any provision of this section.

Credits
(Added by Stats.1969, c. 1333, p. 2680, § 1. Amended by Stats.1979, c. 975, p. 3339, § 1, operative Jan. 1, 1983.)

Editors' Notes

VALIDITY

This section was held unconstitutional as a violation of the dormant Commerce Clause in the decision of National Ass'n of Optometrists & Opticians v. Lockyer, E.D.Cal.2006, 463 F.Supp.2d 1116, reversed and remanded 567 F.3d 521, on remand 709 F.Supp.2d 968.

Notes of Decisions (9)

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West's Ann. Cal. Bus. & Prof. Code § 655, CA BUS & PROF § 655
Current with urgency legislation through Ch. 70 of 2013 Reg.Sess,

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West's Annotated California Codes
Business and Professions Code (Refs & Annos)
Division 2. Healing Arts (Refs & Annos)
Chapter 5.5. Registered Dispensing Opticians (Refs & Annos)
Article 1. General Provisions (Refs & Annos)

West's Ann.Cal.Bus. & Prof.Code § 2556

§ 2556. Unlawful acts

Currentness

It is unlawful to do any of the following: to advertise the furnishing of, or to furnish, the services of a refractionist, an optometrist, or a physician and surgeon; to directly or indirectly employ or maintain on or near the premises used for optical dispensing, a refractionist, an optometrist, a physician and surgeon, or a practitioner of any other profession for the purpose of any examination or treatment of the eyes; or to duplicate or change lenses without a prescription or order from a person duly licensed to issue the same.

Credits
(Added by Stats.1939, c. 955, p. 2694, § 1. Amended by Stats.1979, c. 653, p. 2012, § 9.)

Editors' Notes

VALIDITY

This section was held unconstitutional as a violation of the dormant Commerce Clause in the decision of National Ass'n of Optometrists & Opticians v. Lockyer, E.D.Cal.2006, 463 F.Supp.2d 1116, reversed and remanded 567 F.3d 521, on remand 709 F.Supp.2d 968.

Notes of Decisions (8)

West's Ann. Cal. Bus. & Prof. Code § 2556, CA BUS & PROF § 2556
Current with urgency legislation through Ch. 70 of 2013 Reg.Sess,

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West's Annotated California Codes
Business and Professions Code (Refs & Annos)
Division 2. Healing Arts (Refs & Annos)
Chapter 7. Optometry (Refs & Annos)
Article 5. Revocation and Suspension (Refs & Annos)

West's Ann.Cal.Bus. & Prof.Code § 3109

§ 3109. Accepting employment by improper person or company; incorporation; employment by ophthalmologist

Effective: January 1, 2006

Currentness

Directly or indirectly accepting employment to practice optometry from any person not having a valid, unrevoked license as an optometrist or from any company or corporation constitutes unprofessional conduct. Except as provided in this chapter, no optometrist may, singly or jointly with others, be incorporated or become incorporated when the purpose or a purpose of the corporation is to practice optometry or to conduct the practice of optometry.

The terms "accepting employment to practice optometry" as used in this section shall not be construed so as to prevent a licensed optometrist from practicing optometry upon an individual patient.

Notwithstanding the provisions of this section or the provisions of any other law, a licensed optometrist may be employed to practice optometry by a physician and surgeon who holds a certificate under this division and who practices in the specialty of ophthalmology or by a health care service plan pursuant to the provisions of Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

Credits
(Formerly § 3103, added by Stats.1937, c. 423, p. 1381. Amended by Stats.1970, c. 1265, p. 2283, § 1; Stats.1974, c. 874, p. 1867, § 2; Stats.1979, c. 788, p. 2687, § 6. Renumbered § 3109 and amended by Stats.2005, c. 393 (A.B.488), § 19.)

Notes of Decisions (9)

West's Ann. Cal. Bus. & Prof. Code § 3109, CA BUS & PROF § 3109
Current with urgency legislation through Ch. 70 of 2013 Reg.Sess,

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Barclays Official California Code of Regulations Currentness
Title 16. Professional and Vocational Regulations
Division 13.5. Registered Dispensing Opticians of the Medical Board of California
Article 5. Advertising

16 CCR § 1399.251

§ 1399.251. Advertisement for Eye Examination.

It is unprofessional conduct for a registered dispensing optician to advertise a price or fee for a visual eye examination or a complete medical eye examination or to otherwise advertise the furnishing of the services of an optometrist or a physician and surgeon.

Note: Authority cited: Sections 651 and 2558, Business and Professions Code. Reference: Sections 651, 2540, 2556 and 17500, Business and Professions Code.

This database is current through 7/26/13 Register 2013, No. 30

16 CCR § 1399.251, 16 CA ADC § 1399.251

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Barclays Official California Code of Regulations Currentness
Title 16. Professional and Vocational Regulations
Division 15. State Board of Optometry
Article 3. Professional Rules (Refs & Annos)

16 CCR § 1514

§ 1514. Renting Space from and Practicing on Premises of Commercial (Mercantile) Concern.

Where an optometrist rents or leases space from and practices optometry on the premises of a commercial (mercantile) concern, all of the following conditions shall be met:

(a) The practice shall be owned by the optometrist and in every phase be under his/her exclusive control. The patient records shall be the sole property of the optometrist and free from any involvement with a person unlicensed to practice optometry. The optometrist shall make every effort to provide for emergency referrals.

(b) The rented space shall be definite and apart from space occupied by other occupants of the premises and shall have a sign designating that the rented space is occupied by an optometrist or optometrists.

(c) All signs, advertising, and display shall likewise be separate and distinct from that of the other occupants and have the optometrist's name and the word "optometrist" prominently displayed in connection therewith.

(d) There shall be no legends as "Optical Department," "Optometrical Department," "Optical Shoppe," or others of similar import, displayed on any part of the premises or in any advertising.

(e) There shall be no linking of the optometrist's name, or practice, in advertising or in any other manner with that of the commercial (mercantile) concern from whom he/she is leasing space.

Note: Authority cited: Sections 3025 and 3025.5, Business and Professions Code. Reference: Sections 651 and 3025, Business and Professions Code.

HISTORY

1. Amendment filed 12-1-83; effective thirtieth day thereafter (Register 83, No. 49).

2. Amendment of subsection (b) filed 9-25-2012; operative 10-25-2012 (Register 2012, No. 39).

This database is current through 7/26/13 Register 2013, No. 30

16 CCR § 1514, 16 CA ADC § 1514

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MEDICAL BOARD OF CALIFORNIA

DATE REPORT ISSUED: January 21, 2014
ATTENTION: Board Members
SUBJECT: Executive Summary – Licensing Program
STAFF CONTACT: Curtis J. Worden, Chief of Licensing

STAFFING:
The Licensing Program has faced some challenges in the second quarter of FY 13/14. Licensing has had several staff out for various reasons, including extended leaves and position vacancies. The most challenging issue has been the implementation of the new Department of Consumer Affairs, BreEZe computer system and the need to input additional information.

Licensing currently has the following vacancies:

- 2 - OTs - Call Center – Interviews have been conducted
- 2 - SSAs - IMG Physicians and Surgeons (P&S) Applications – Interviews have been conducted
- 1 - AGPA - Midwife, Outpatient Surgery Settings, Research Psychoanalyst and Medical Assistances – Position has been advertised
-

STATISTICS:
The statistics start on page BRD 26A - 4 through BRD 26A - 5. Please note that most of the statistics that I normally provide are unavailable at this time due to the implementation of BreEZe. The statistics that have been provided have been obtained either by a manual count or are not part of the BreEZe system.

Notable statistics include:

- Consumer Information Unit, telephone calls answered - 21,921 (BRD 26A - 4)
- Consumer Information Unit, telephone calls abandoned - **8,058** (BRD 26A - 4)
    - Approximately 2.5 times higher than the previous quarter
- Consumer Information Unit, telephone calls requesting a call back - **8,542** (BRD 26A - 4)
    - Approximately 2.2 times higher than the previous quarter
- The following statistics are for the work ISB staff did to assist Licensing:
    - Consumer/Licensee/Applicant phone calls answered by the ISB staff - **2,488**
    - Address changes completed by ISB staff - **2,225**
- P&S applications initial review completed - *674* This was gathered by other means than BreEZe and has a margin of error
- P&S applications not reviewed - *1004* This was gathered by other means than BreEZe and has a margin of error
- P&S applications pending - *6847* This was gathered by other means than BreEZe and has a margin of error
- P&S licenses issued - **849**
    - This number is a decrease of 598 licenses from the previous quarter and decrease of 415 licenses compared to the same timeframe in FY 12/13

Licensing did not meet its goal of performing initial reviews of all new P&S applications within 45 days of being received by the Board for all of the 13 weeks in the second quarter of FY 13/14 (page BRD 26A - 12). BreEZe has increased the amount of time to process applications and has significantly impacted staffs' ability to meet the goal. The Licensing management will continue to monitor the review dates closely and is working with staff to reach the Board's goals in the future.

INTERNATIONAL MEDICAL SCHOOLS:
The statistics for the International Medical School Reviews are on page BRD 26A - 5.
The review of International Medical Schools continues to be a demanding workload for the Board. There are currently three Self-Assessment Reports that are being reviewed by Licensing Medical Consultants.

OUTPATIENT SURGERY SETTINGS:
January 22, 2014, the Board held an interested parties meeting regarding possible revisions to current statutes and regulations regarding Outpatient Surgery Settings. The main location of this meeting was at the Board's Sacramento Headquarters. This meeting was also video conferenced at the following Board District Offices:

Cerritos District Office
San Diego District Office
San Jose District Office

Please see the information in Agenda Item 27.

SPONSORED FREE HEALTHCARE EVENTS:
The Board received one application from a physician and surgeon licensed in another state to participate in the October 31 through November 3, 2013, Care Harbor / LA 2013 event at the Los Angeles Sports Arena, 3939 South Figueroa Ave., Los Angeles, CA. However, this applicant withdrew his application. The Board did not receive the required fingerprint criminal record check for this applicant.

PHYSICIAN SPECIALTY BOARD APPLICATIONS:
The Board previously had one pending application from a physician specialty board requesting approval by the Board. The Board still has a pending renewal request.

LICENSING – BREEZE UPDATE:
The Licensing subject matter experts (specific managers, lead analysts and other staff) started working in the BreEZe system on October 8, 2013, to identify any specific areas of concern and determine how to use the workarounds that were needed for the areas that are not functioning as expected. This was necessary to provide the rest of the Licensing staff with the correct procedures to use and to provide any training needed.

Prior to BreEZe the Board had an online lookup (WAAS) that P&S applicants could use to determine what documents the Board received and if the documents had been reviewed. At this

time, BreEZe currently does not have a similar feature that works as requested by the Board and is useful to applicants at this time. This has resulted in a large number of telephone calls regarding application status and if the Board has received specific documents.

The Consumer Information Unit (CIU) is attempting to answer as many calls as possible. However, many of the telephone calls are taking up to 20 minutes each due to questions regarding BreEZe and needing to assist physicians who are trying to renew their licenses. The CIU is experiencing more calls than the Board is staffed to handle for the length of time each call needs. Therefore, callers are experiencing longer wait times.

The Board's Information Systems Branch (ISB) staff has and continues to provide outstanding service and assistance to the Licensing staff during the BreEZe project. The ISB staff is handling all of the calls related to technical problems regarding BreEZe and recently started taking calls from applicants regarding application information. ISB's assistance is greatly appreciated by Licensing.

The online P&S renewal process was not functioning for most of the month of October 2013 and the paper renewal remittent processor was not processing renewals correctly. This resulted in almost all of the renewals being processed manually by staff and large increases in telephone calls regarding license renewals. Some of these issues have been corrected. However, staff is still required to process or provide assistance to many of the physicians who are renewing each month. The Board renews approximately 5,000 P&S licenses a month.

Currently, with the learning curve, additional information needed and workarounds, it takes more than twice as long to enter information in BreEZe than the previous systems.

As the Board has been using the new BreEZe system, the Licensing managers and the lead analysts have been identifying areas to assist staff with new procedures and additional training as needed on an ongoing basis. One area that has been identified is that the staff may benefit from having dual monitors to assist in reducing time it takes to work in BreEZe. We will be testing if one of the monitors should be a touch screen monitor to help staff work in BreEZe more efficiently. In addition, Licensing will be implementing changes (temporary and possibly permanent) to assist staff to reduce the timeframes for the initial review of applications. Some of these changes will be implemented within the next two weeks and any additional changes will be identified and made during the month of February.

WORKLOAD REPORT
as of December 31, 2013

CONSUMER INFORMATION UNIT FY 13/14					
	FY 13/14	Q1	Q2	Q3	Q4
Total Calls Answered	**46,818**	24,897	21,921		
Calls Requesting Call Back	**12,403**	3,861	8,542		
Calls Abandoned	**11,205**	3,147	8,058		
Address Changes Completed	**1,674**	1,674			

CONSUMER INFORMATION UNIT FY 12/13					
	FY 12/13	Q1	Q2	Q3	Q4
Total Calls Answered	**92,611**	26,022	20,578	22,607	23,404
Calls Requesting Call Back	**12,469**	2,850	2,516	3,493	3,610
Calls Abandoned	**11,068**	3,071	2,167	2,832	2,998
Address Changes Completed	**5,067**	2,046	1,373	835	813

SR 2 - CATEGORIES FY 13/14					
	FY 13/14	Q1	Q2	Q3	Q4
Alcohol/Drugs	**5**	5	0		
PG/Medical Knowledge	**28**	19	9		
Convictions	**16**	11	5		
Other	**45**	29	16		

SR 2 - CATEGORIES FY 12/13					
	FY 12/13	Q1	Q2	Q3	Q4
Alcohol/Drugs	**41**	5	9	3	24
PG/Medical Knowledge	**89**	25	19	13	32
Convictions	**51**	15	5	2	29
Other	**111**	11	19	17	64

WORKLOAD REPORT
as of December 31, 2013

INTERNATIONAL MEDICAL SCHOOL APPLICATIONS FY 13/14					
	FY 13/14	**Q1**	**Q2**	**Q3**	**Q4**
Schools Pending Recognition at Beginni	**N/A**	98	102		
Pending Self-Assessment Reports	**N/A**	9	10		
New Self-Assessment Reports Receivec	**1**	1	0		
New Unrecognized Schools Received	**46**	21	25		
School Recognized Pursuant to CC	**41**	18	23		
School Recognized Pursuant to CC	**0**	0	0		
TOTAL Schools Pending Recognition at	**N/A**	102	104		

INTERNATIONAL MEDICAL SCHOOL APPLICATIONS FY 12/13					
	FY 12/13	**Q1**	**Q2**	**Q3**	**Q4**
Schools Pending Recognition at Beginni	**N/A**	101	98	94	91
Pending Self-Assessment Reports	**N/A**	7	9	8	8
New Self-Assessment Reports Receivec	**2**	0	2	0	0
New Unrecognized Schools Received	**96**	27	24	17	28
School Recognized Pursuant to CC	**104**	30	33	19	22
School Recognized Pursuant to CC	**1**	0	0	1	0
TOTAL Schools Pending Recognition at	**N/A**	98	94	91	97

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED:	January 23, 2014
ATTENTION:	Members, Medical Board of California
SUBJECT:	USMLE Passing Scores
FROM:	Curt Worden, Chief of Licensing Kerrie Webb, Senior Staff Counsel

REQUESTED ACTION:

Make a motion to reaffirm the Medical Board of California's (Board) practice of accepting the passing score set by the Federation of State Medical Boards as its own passing score on all Steps of the United States Medical Licensing Examination (USMLE).

BACKGROUND:

One of the requirements for an applicant for a physician's and surgeon's certificate is the successful completion of Steps I, II, and III of the USMLE. The creation and administration of the examination is a collaborative effort by the USMLE, the Federation of State Medical Boards and the National Board of Medical Examiners (collectively referred to herein as FSMB). Section 2177 of the Business and Professions Code requires a passing score for an entire examination or for each part of the required licensing examination, as established by the Board. An applicant must pass Step 3 within not more than four attempts in order to be eligible for licensure. However, an applicant who obtains a passing score on Step 3 in more than four attempts, and who meets the requirements of Section 2135.5, is eligible to be considered for licensure.

Pursuant to case law, the Board is required to establish by formal resolution the passing scores for the USMLE for California.

The recommended minimum passing level is reviewed periodically and may be adjusted by the FSMB at any time. For example, at its December 2013 meeting, the Step 1 Committee conducted a review of the USMLE Step 1 examination minimum passing score. As a result of its review, the Step 1 Committee decided to raise the recommended Step 1 minimum passing score from 188 to 192. Similarly, the method in which the scores are reported are reviewed and adjusted as needed.

In the past, the Board has relied on a scaled two-digit score, which is derived from the three-digit score in such a way that a score of 75 corresponds to the minimum passing score . The two-digit score is not as accurate as the three-digit score, and the FSMB is moving away from reporting scores on the two-digit scale. Accordingly, staff recommends the Board remove the reference to the specific passing score of 75, and accept the passing score set by the FSMB as its own passing score on all Steps of the USMLE.

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: January 29, 2014
ATTENTION: Members, Medical Board of California
SUBJECT: Outpatient Surgery Settings Task Force
STAFF CONTACT: Curtis J. Worden, Chief of Licensing

REQUESTED ACTION:
Review and approve the proposed amendment to Health and Safety Code (HSC) Section 1248.15(a)(6)(B)(i) regarding peer review requirements for physicians in Outpatient Surgery Settings (OSS). Direct staff to seek legislation for this proposed amendment.

BACKGROUND:
On January 22, 2014, the OSS Task Force held an interested parties meeting regarding proposed amendments to the OSS statutes and regulations.

The OSS Task Force meeting was held at the Medical Board of California (MBC) Headquarters in Sacramento and was video conferenced to three MBC District Offices located in Cerritos, San Jose, and San Diego. The OSS Task Force provided the interested parties with the language and reasons for the recommended changes to the statutes and regulations, and requested input on these changes.

At the October 2013 Board Meeting, the OSS Task Force was authorized to move forward with its recommended changes after receiving and considering input from the interested parties at the January 22, 2014 meeting. Based upon the comments from the interested parties on January 22, 2014, the OSS Task Force determined three legislative changes could move forward. Therefore, the language for these changes was provided to the Senate Business, Professions, and Economic Development Committee Staff, as Senator Lieu will be authoring a bill for these changes.

Specifically, the OSS Task Force recommended changes to:

1) HSC Section 1248.15(a)(2)(D) – providing some clean up language;
2) HSC Sections 1248.3(a) – requiring initial certifications of accreditation to be valid for only two years, instead of three; and
3) HSC Section 1248.35(b)(2) – requiring inspections, after the initial inspection, to be unannounced.

See **Attachment 1** for the specific language.

In addition to the above statutory changes, the OSS Task Force determined the Board needed to make some conforming changes to the regulations based upon recent legislative changes. Specifically, changes needed to be made to Section 1314.4 of the California Code of Regulations, Title 16. No comments requiring modification to these suggested changes were received at the interested parties meeting. Therefore, staff will begin the regulatory process to make these conforming changes. See **Attachment 2** for the specific regulatory changes.

At the interested parties meeting, there were two of the suggested amendments that received a significant amount of comments. The first amendment, which received extensive comments, was the deletion of HSC Section 1248.15(a)(2)(C)(iii). This recommended deletion would have removed one of the methods whereby an OSS can be accredited. Based upon the comments received, the OSS Task Force has determined that more discussion is needed.

The other amendment that received some significant input was the change to HSC Section 1248.15(a)(6)(B)(i), which requires peer review for all physicians in an OSS even if there is only one physician performing procedures in the OSS. The interested parties requested the Board provide more clarification and also provide a definition for peer review. The OSS Task Force has discussed the comments received by the interested parties and has modified the proposed section based upon these comments.

The OSS Task Force is requesting the Board Members review and approve the newly revised amendment to this section prior to providing the language to Legislative Staff for inclusion into a bill. The recommended change is found on page BRD 27-4.

The changes are identified below in ~~strikethrough~~ – indicating a recommendation to delete the section/word, and underline – indicating an addition to the section. After each deletion/addition is a highlighted section indicating the reason for the recommended change.

HEALTH AND SAFETY CODE

Section 1248.15.

(a) The board shall adopt standards for accreditation and, in approving accreditation agencies to perform accreditation of outpatient settings, shall ensure that the certification program shall, at a minimum, include standards for the following aspects of the settings' operations:

(1) Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.

(2) (A) Outpatient settings shall have a system for facility safety and emergency training requirements.

(B) There shall be onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided.

(C) In order for procedures to be performed in an outpatient setting as defined in Section 1248, the outpatient setting shall do one of the following:

(i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff.

(ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may be precluded from having admitting privileges by their professional classification or other administrative limitations, shall have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.

~~(iii) Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies that shall be reviewed at the time of accreditation. No reasonable plan shall be disapproved by the accrediting agency.~~

The above pathway does not adequately provide consumer protection.

(D) ~~In addition to the requirements imposed in subparagraph (C), t~~ *T*he outpatient setting shall submit for approval by an accreditation agency at the time of accreditation a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm or to govern emergency and urgent care situations. The plan shall include, at a minimum, that if a patient is being transferred to a local accredited or licensed acute care hospital, the outpatient setting shall do all of the following:

The above language should be stricken because an outpatient surgery setting must comply with each of the subsections, and it does not have to start with "in addition to..."

(i) Notify the individual designated by the patient to be notified in case of an emergency.

(ii) Ensure that the mode of transfer is consistent with the patient's medical condition.

(iii) Ensure that all relevant clinical information is documented and accompanies the patient at the time of transfer.

(iv) Continue to provide appropriate care to the patient until the transfer is effectuated.

(E) All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the outpatient setting, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported, as appropriate, to the accrediting body or in accordance with existing law.

(3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of Division 2 of the Business and Professions Code.

(4) Outpatient settings shall have a system for maintaining clinical records.

(5) Outpatient settings shall have a system for patient care and monitoring procedures.

(6) (A) Outpatient settings shall have a system for quality assessment and improvement.

(B) Members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of privileges granted. The outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.

(i) All physicians who perform procedures for which accreditation is required in the outpatient setting are required to have peer review evaluations as defined in Business and Professions Code Section 805 (a)(1)(A), including outpatient settings that only have one physician. For purposes of this section, a peer review body consists of California licensed physicians who are qualified by education and experience in performing the same types of procedures, who may or may not have privileges at the outpatient setting.

The above additional language is needed to enhance consumer protection since a physician who owns his or her own outpatient setting may choose not to have peer

review of his or her practice. This will also help ensure all physicians who are performing procedures in an outpatient setting are subject to peer review.

(C) Clinical privileges shall be periodically reappraised by the outpatient setting. The scope of procedures performed in the outpatient setting shall be periodically reviewed and amended as appropriate.

(7) Outpatient settings regulated by this chapter that have multiple service locations shall have all of the sites inspected.

(8) Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.

(9) Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.

(10) Outpatient settings shall have a written discharge criteria.

(b) Outpatient settings shall have a minimum of two staff persons on the premises, one of whom shall either be a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care. Transfer to an unlicensed setting of a patient who does not meet the discharge criteria adopted pursuant to paragraph (10) of subdivision (a) shall constitute unprofessional conduct.

(c) An accreditation agency may include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.

(d) No accreditation standard adopted or approved by the board, and no standard included in any certification program of any accreditation agency approved by the board, shall serve to limit the ability of any allied health care practitioner to provide services within his or her full scope of practice. Notwithstanding this or any other provision of law, each outpatient setting may limit the privileges, or determine the privileges, within the appropriate scope of practice, that will be afforded to physicians and allied health care practitioners who practice at the facility, in accordance with credentialing standards established by the outpatient setting in compliance with this chapter. Privileges may not be arbitrarily restricted based on category of licensure.

(e) The board shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.

(f) The board may adopt regulations it deems necessary to specify procedures that should be performed in an accredited outpatient setting for facilities or clinics that are outside the definition of outpatient setting as specified in Section 1248.

(g) As part of the accreditation process, the accrediting agency shall conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest therein, to determine whether there have been any adverse accreditation decisions rendered against them. For the purposes of this section, “conducting a reasonable investigation” means querying the Medical Board of California and the Osteopathic Medical Board of California to ascertain if either the outpatient setting has, or, if its

owners are licensed physicians and surgeons, if those physicians and surgeons have, been subject to an adverse accreditation decision.

(Amended by Stats. 2013, Ch. 515, Sec. 36. Effective January 1, 2014.)

Section 1248.3.

(a) *Initial certificates of accreditation shall be valid for not more than two years and renewal c*~~C~~ertificates of accreditation issued to outpatient settings by an accreditation agency shall be valid for not more than three years.

The above proposed language revision will enhance consumer protection by ensuring that a newly accredited outpatient surgery setting has its first renewal inspection as soon as 18 months and no later than two years.

(b) The outpatient setting shall notify the accreditation agency within 30 days of any significant change in ownership, including, but not limited to, a merger, change in majority interest, consolidation, name change, change in scope of services, additional services, or change in locations.

(c) Except for disclosures to the division or to the Division of Medical Quality under this chapter, an accreditation agency shall not disclose information obtained in the performance of accreditation activities under this chapter that individually identifies patients, individual medical practitioners, or outpatient settings. Neither the proceedings nor the records of an accreditation agency or the proceedings and records of an outpatient setting related to performance of quality assurance or accreditation activities under this chapter shall be subject to discovery, nor shall the records or proceedings be admissible in a court of law. The prohibition relating to discovery and admissibility of records and proceedings does not apply to any outpatient setting requesting accreditation in the event that denial or revocation of that outpatient setting's accreditation is being contested. Nothing in this section shall prohibit the accreditation agency from making discretionary disclosures of information to an outpatient setting pertaining to the accreditation of that outpatient setting.

(Added by Stats. 1994, Ch. 1276, Sec. 2. Effective January 1, 1995.)

Section 1248.35.

(a) Every outpatient setting which is accredited shall be inspected by the accreditation agency and may also be inspected by the Medical Board of California. The Medical Board of California shall ensure that accreditation agencies inspect outpatient settings.

(b) Unless otherwise specified, the following requirements apply to inspections described in subdivision (a).

(1) The frequency of inspection shall depend upon the type and complexity of the outpatient setting to be inspected.

(2) Inspections shall be conducted no less often than once every three years by the accreditation agency and as often as necessary by the Medical Board of California to ensure the quality of care provided*. After the initial inspection for accreditation, all subsequent inspections shall be unannounced.*

The above revision will enhance consumer protection since the inspections will be unannounced. The outpatient surgery setting will be more likely to consistently maintain compliance with the minimum standards for accreditation, since the

outpatient surgery setting will not know when the accreditation agency inspection team will arrive for the inspection.

(3) The Medical Board of California or the accreditation agency may enter and inspect any outpatient setting that is accredited by an accreditation agency at any reasonable time to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of this chapter.

(c) If an accreditation agency determines, as a result of its inspection, that an outpatient setting is not in compliance with the standards under which it was approved, the accreditation agency may do any of the following:

(1) Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the outpatient setting's accreditation.

(2) Issue a reprimand.

(3) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the board or the accreditation agency, to correct the deficiencies.

(4) Suspend or revoke the outpatient setting's certification of accreditation.

(d) (1) Except as is otherwise provided in this subdivision, before suspending or revoking a certificate of accreditation under this chapter, the accreditation agency shall provide the outpatient setting with notice of any deficiencies and the outpatient setting shall agree with the accreditation agency on a plan of correction that shall give the outpatient setting reasonable time to supply information demonstrating compliance with the standards of the accreditation agency in compliance with this chapter, as well as the opportunity for a hearing on the matter upon the request of the outpatient setting. During the allotted time to correct the deficiencies, the plan of correction, which includes the deficiencies, shall be conspicuously posted by the outpatient setting in a location accessible to public view. Within 10 days after the adoption of the plan of correction, the accrediting agency shall send a list of deficiencies and the corrective action to be taken to the board and to the California State Board of Pharmacy if an outpatient setting is licensed pursuant to Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code. The accreditation agency may immediately suspend the certificate of accreditation before providing notice and an opportunity to be heard, but only when failure to take the action may result in imminent danger to the health of an individual. In such cases, the accreditation agency shall provide subsequent notice and an opportunity to be heard.

(2) If an outpatient setting does not comply with a corrective action within a timeframe specified by the accrediting agency, the accrediting agency shall issue a reprimand, and may either place the outpatient setting on probation or suspend or revoke the accreditation of the outpatient setting, and shall notify the board of its action. This section shall not be deemed to prohibit an outpatient setting that is unable to correct the deficiencies, as specified in the plan of correction, for reasons beyond its control, from voluntarily surrendering its accreditation prior to initiation of any suspension or revocation proceeding.

(e) The accreditation agency shall, within 24 hours, report to the board if the outpatient setting has been issued a reprimand or if the outpatient setting's

certification of accreditation has been suspended or revoked or if the outpatient setting has been placed on probation. If an outpatient setting has been issued a license by the California State Board of Pharmacy pursuant to Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code, the accreditation agency shall also send this report to the California State Board of Pharmacy within 24 hours.

(f) The accreditation agency, upon receipt of a complaint from the board that an outpatient setting poses an immediate risk to public safety, shall inspect the outpatient setting and report its findings of inspection to the board within five business days. If an accreditation agency receives any other complaint from the board, it shall investigate the outpatient setting and report its findings of investigation to the board within 30 days.

(g) Reports on the results of any inspection shall be kept on file with the board and the accreditation agency along with the plan of correction and the comments of the outpatient setting. The inspection report may include a recommendation for reinspection. All final inspection reports, which include the lists of deficiencies, plans of correction or requirements for improvements and correction, and corrective action completed, shall be public records open to public inspection.

(h) If one accrediting agency denies accreditation, or revokes or suspends the accreditation of an outpatient setting, this action shall apply to all other accrediting agencies. An outpatient setting that is denied accreditation is permitted to reapply for accreditation with the same accrediting agency. The outpatient setting also may apply for accreditation from another accrediting agency, but only if it discloses the full accreditation report of the accrediting agency that denied accreditation. Any outpatient setting that has been denied accreditation shall disclose the accreditation report to any other accrediting agency to which it submits an application. The new accrediting agency shall ensure that all deficiencies have been corrected and conduct a new onsite inspection consistent with the standards specified in this chapter.

(i) If an outpatient setting's certification of accreditation has been suspended or revoked, or if the accreditation has been denied, the accreditation agency shall do all of the following:

(1) Notify the board of the action.

(2) Send a notification letter to the outpatient setting of the action. The notification letter shall state that the setting is no longer allowed to perform procedures that require outpatient setting accreditation.

(3) Require the outpatient setting to remove its accreditation certification and to post the notification letter in a conspicuous location, accessible to public view.

(j) The board may take any appropriate action it deems necessary pursuant to Section 1248.7 if an outpatient setting's certification of accreditation has been suspended or revoked, or if accreditation has been denied.

(Amended by Stats. 2012, Ch. 454, Sec. 5. Effective January 1, 2013.)

California Code of Regulations (CCR)

Title 16. Professional and Vocational Regulations

Division 13. Medical Board of California

Chapter 1. ~~Division of~~ Licensing

There is no longer a Division of Licensing within the Board

Section 1313.4. Standards.

(a) An accreditation agency shall meet the standards set forth in sections 1248.15 and 1248.4 of the Health and Safety Code.

(1) With respect to section 1248.15(a)(2)(C)(i), a written transfer agreement shall include a mechanism for patient transport; a plan for transfer of the patient's records; policies defining the role of each person in handling an emergency; and a plan for continuity of the patient's care upon transfer of that care.

(2) With respect to section 1248.15(a)(6), the required system for quality assessment and improvement shall include, in addition to chart review, actions that utilize information derived through quality assessment to improve systems to maximize patient protection.

~~(3) With respect to section 1248.15(a)(7), the actual sample size shall be determined by the accreditation agency.~~

CCR § 1314.4 (3) is no longer applicable since statute now requires all locations to be inspected.

(b) An accreditation agency shall send to the ~~division~~ *board* any change in its accreditation standards within 30 calendar days after making the change.

~~(c) An accreditation agency shall, within fourteen calendar days after issuance, provide to the division a copy of any certificates of accreditation it issues and any denial or revocation of a certificate of accreditation. For each setting whose accreditation it denies or revokes, the accreditation agency shall also provide to the division in writing the reasons for its action.~~

CCR § 1314.4 (c) is no longer applicable since HSC §1248.25 now requires notification to the Board in three business days of denials. In addition, HSC §1248.35(e) requires notification to the Board within 24 hours if an accreditation agency has issued an outpatient surgery setting a reprimand, suspension, revocation, or put an outpatient surgery setting on probation.

Note: Authority cited: Sections 2018 and 2217, Business and Professions Code; and Section 1248.15, Health and Safety Code. Reference: Sections 1248.15 and 1248.4, Health and Safety Code.

MEDICAL BOARD OF CALIFORNIA
Status of Pending Regulations

Subject	Current Status	Date Approved by Board	Date Notice Published by OAL	Date of Public Hearing	Date of Final Adoption by Board	Date to DCA (and other control agencies) for Final Review *	Date to OAL for Review **	Date to Sec. of State***
Implementation of SB 1441	Set for discussion at Board meeting on 02/06/14	07/19/13	09/06/13	10/25/13		08/30/13 DCA for review and approval		
PA – Supervision Requirements	Hearing set for 02/07/14	10/25/13	12/13/13	02/07/14		12/03/13 to DCA for review and approval		

Prepared by Chris Valine
Updated January 22, 2014
For questions, call (916) 263-2466

DCA is allowed 30 calendar days for review.
OAL is allowed 30 working days for review.
Rulemakings become effective on a quarterly basis, unless otherwise specified.

MEDICAL BOARD OF CALIFORNIA - 2013 TRACKER LIST
January 29, 2014

BILL	AUTHOR	TITLE	STATUS	POSITION	AMENDED
AB 186	Maienschein	Professions & Vocations: Military Spouses: Temporary Licenses	Sen. B&P	Support – 2-year Bill	6/24/13
AB 496	Gordon	Task Force: LGBTI Cultural Competency	Inactive File	Support – 2-year Bill	6/25/13
AB 809	Logue	Healing Arts: Telehealth	Sen. Health	Support – 2-year Bill	6/25/13
AB 831	Bloom	Drug Overdoses	Held in Approps.	Support – 2-year Bill	4/3/13
AB 860	Perea	Medical School Scholarships	Held in Approps.	Support – 2-year Bill	4/8/13
AB 916	Eggman	Healing Arts: False or Misleading Advertising	Sen. B&P	Support – 2-year Bill	Intro.
AB 1176	Bocanegra & Bonta	Medical Residency Training Program Grants	Held in Approps.	Support – 2-year Bill	4/23/13
AB 1182	Brown	Medically Underserved Areas	Assembly	SPOT	Intro.
AB 1269	Gray	Medicine: Special Faculty Permit	Asm. B&P	SPOT	Intro.
AB 1535	Bloom	Pharmacists: Naloxone Hydrochloride	Introduced	Reco: Support	Intro
SB 20	Hernandez	Health Care: Workforce Training	Held in Approps.	Support – 2-year Bill	2/14/13
SB 439	Steinberg	Medical Marijuana	Asm. Health	2-year Bill	8/5/13
SB 491	Hernandez	Nurse Practitioners	Held in Approps.	Oppose – 2-year Bill	8/14/13
SB 492	Hernandez	Optometrist Practice: Licensure	Asm. B&P	OUA – 2-year Bill	8/5/13
SB 500	Lieu	Medical Practice: Pain Management	Assembly	Reco: Support	1/9/14
SB 796	Nielsen	Medicine: Physicians and Surgeons	Senate	SPOT	Intro.

Green – For Discussion, Blue – Spot or 2-year Bill

2014 TENTATIVE LEGISLATIVE CALENDAR

COMPILED BY THE OFFICES OF THE SECRETARY OF THE SENATE & THE ASSEMBLY CHIEF CLERK

October 22, 2013

JANUARY						
S	M	T	W	TH	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

FEBRUARY						
S	M	T	W	TH	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	

MARCH						
S	M	T	W	TH	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

APRIL						
S	M	T	W	TH	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

DEADLINES

Jan. 1 Statutes take effect (Art. IV, Sec. 8(c)).

Jan. 6 Legislature Reconvenes (J.R. 51(a)(4)).

Jan. 10 Budget must be submitted by Governor (Art. IV, Sec. 12(a)).

Jan. 17 Last day for **policy committees** to hear and report to Fiscal committees fiscal bills introduced in their house in 2013 (J.R. 61(b)(1)).

Jan. 20 Martin Luther King, Jr. Day.

Jan. 24 Last day for any committee to hear and report to the **Floor** bills introduced in their house in 2013 (J.R. 61(b)(2)). Last day to submit **bill requests** to the Office of Legislative Counsel.

Jan. 31 Last day for each house to **pass bills introduced in 2013** in their House (Art. IV, Sec. 10(c)), (J.R. 61(b)(3)).

Feb. 17 President's Day.

Feb. 21 Last day for bills to be **introduced** (J.R. 61(b)(4)), (J.R. 54(a)).

Mar. 31 Cesar Chavez Day

Apr. 10 **Spring Recess** begins at end of this day's session (J.R. 51(b)(1)).

Apr. 21 Legislature reconvenes from **Spring Recess** (J.R. 51(b)(1)).

2014 TENTATIVE LEGISLATIVE CALENDAR

COMPILED BY THE OFFICES OF THE SECRETARY OF THE SENATE & THE ASSEMBLY CHIEF CLERK

October 22, 2013

MAY						
S	M	T	W	TH	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

May 2 Last day for **policy committees** to hear and report to Fiscal Committees **fiscal bills** introduced in their house (J.R. 61(b)(5)).

May 9 Last day for **policy committees** to hear and report to the floor **non-fiscal** bills introduced in their house (J.R. 61(b)(6)).

May 16 Last day for **policy committees** to meet prior to June 2 (J.R. 61(b)(7)).

May 23 Last day for **fiscal committees** to hear and report to the floor Bills introduced in their house (J.R. 61(b)(8)). Last day for **fiscal Committees** to meet prior to June 2 (J.R. 61 (b)(9)).

May 26 Memorial Day

May 27 - 30 Floor Session Only. No committee may meet for any purpose (J.R. 61(b)(10)).

May 30 Last day for bills to be **passed out of the house of origin** (J.R. 61(b)(11)).

JUNE						
S	M	T	W	TH	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

June 2 Committee meetings may resume (J.R. 61(b)(12)).

June 15 **Budget** must be **passed** by **midnight** (Art. IV, Sec. 12(c)(3)).

June 26 Last day for a legislative measure to qualify for the November 4 general election ballot (Election code Sec. 9040).

June 27 Last day for **policy committees** to meet and report bills (J.R. 61(b)(13)).

JULY						
S	M	T	W	TH	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

July 3 **Summer Recess** begins at the end of this day's session if Budget Bill has been passed (J.R. 51(b)(2)).

July 4 Independence Day

AUGUST						
S	M	T	W	TH	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

Aug. 4 Legislature reconvenes from **Summer Recess** (J.R. 51(b)(2)).

Aug. 15 Last day for **fiscal committees** to meet and report bills to the Floor (J.R. 61(b)(14)).

Aug. 18 – 31 Floor Session only. No committees, other than conference committees and Rules committee, may meet for any purpose (J.R. 61(b)(15)).

Aug. 22 Last day to **amend bills** on the Floor (J.R. 61(b)(16)).

Aug. 31 Last day for **each house to pass bills** (Art. IV, Sec. 10(c)), (J.R. 61(b)(17)). **Final recess** begins at the end of this day's session (J.R. 51(b)(3)).

2014 TENTATIVE LEGISLATIVE CALENDAR

COMPILED BY THE OFFICES OF THE SECRETARY OF THE SENATE & THE ASSEMBLY CHIEF CLERK

October 22, 2013

IMPORTANT DATES OCCURRING DURING FINAL RECESS

2014

Sept. 30	Last day for Governor to sign or veto bills passed by the Legislature before Sept. 1 and in the Governor's possession on or after Sept. 1 (Art. IV, Sec. 10(b)(2)).
Nov. 4	General Election
Nov. 30	Adjournment Sine Die at midnight (Art. IV, Sec. 3(a)).
Dec. 1	12 m. convening of 2015-16 Regular Session (Art. IV, Sec. 3(a)).

2015

Jan. 1	Statutes take effect (Art. IV, Sec. 8(c)).
Jan. 5	Legislature reconvenes (JR 51(a)(1)).

MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: AB 1535
Author: Bloom
Bill Date: January 21, 2014, Introduced
Subject: Pharmacists: Naloxone Hydrochloride
Sponsor: Drug Policy Alliance
California Pharmacists Association

DESCRIPTION OF CURRENT LEGISLATION:

This bill allows pharmacists to furnish naloxone hydrochloride in accordance with standardized procedures developed by the pharmacist and an authorized prescriber acting within the scope of his or her practice, or in accordance with standardized procedures or protocols developed and approved by the Board of Pharmacy (BOP) and the Medical Board of California (Board). This bill would require a pharmacist to complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride, before furnishing naloxone hydrochloride.

BACKGROUND

Naloxone is used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdosing person to breathe normally. Naloxone is a non-scheduled, inexpensive prescription medication with the same level of regulation as ibuprofen. Naloxone only works if a person has opioids in their system, and has no effect if opioids are absent.

According to the fact sheet, public health experts agree that increasing access to naloxone is a key strategy in preventing drug overdose deaths. The American Medical Association, the White House Office of National Drug Control Policy, the Director of the National Institutes of Drug Abuse, among others, have called for providing naloxone to at-risk patients, first responders, and persons likely to witness a potentially fatal opioid overdose.

ANALYSIS

AB 635 (Ammiano, Chapter 707, Statutes of 2013) was signed into law by the Governor and was supported by the Board. This new law allows health care providers to prescribe, dispense, and issue standing orders for an opioid antagonist to persons at risk of overdose, or their family member, friend, or other person in a position to assist persons at risk, without making them professionally, civilly or criminally liable, if acting within reasonable care. It also extends this same liability protection to individuals assisting in dispensing, distributing, or administering the opioid antagonist during an overdose. This law requires a person who is prescribed or possesses an opioid antagonist pursuant to a standing order to

receive training provided by an opioid overdose prevention and treatment training program.

This bill would further increase access to naloxone by allowing community pharmacists to provide naloxone to at-risk patients pursuant to standardized procedures developed by the pharmacist and an authorized prescriber acting within the scope of his or her practice, or in accordance with standardized procedures or protocols developed and approved by BOP and the Board. This bill would also require a pharmacist to complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride, before furnishing naloxone hydrochloride.

Drug overdoses are now the leading cause of injury death in the United States, surpassing motor vehicle crash deaths. The Board supported AB 635 because it encourages licensed healthcare providers to begin prescribing naloxone to patients on chronic opioid pain medications in order to help address the prescription drug overdose epidemic, furthering the Board's mission of consumer protection. This bill will also increase at-risk patient's access to naloxone, while at the same time ensuring standardized procedures and protocols are in place. Board staff is suggesting that the Board take a support position on this bill

FISCAL: Minimal and absorbable fiscal to develop standardized procedures and protocols with the BOP.

SUPPORT: California Pharmacists Association (sponsor) and Drug Policy Alliance (Sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Support

ASSEMBLY BILL No. 1535

Introduced by Assembly Member Bloom

January 21, 2014

An act to add Section 4052.01 to the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 1535, as introduced, Bloom. Pharmacists: naloxone hydrochloride.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law, generally, authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription. Existing law authorizes a pharmacist to furnish emergency contraceptives and hormonal contraceptives pursuant to standardized procedures or protocols developed and approved by both the board and the Medical Board of California, as specified, or developed by the pharmacist and an authorized prescriber. Existing law also authorizes a pharmacist to furnish nicotine replacement products pursuant to standardized procedures or protocols developed and approved by both the board and the Medical Board of California, as specified. Existing law authorizes a licensed health care provider who is permitted to prescribe an opioid antagonist and is acting with reasonable care to prescribe and dispense or distribute an opioid antagonist for the treatment of an opioid overdose to a person at risk of an opioid-related overdose or a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose.

This bill would authorize a pharmacist to furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber or developed and approved by both the board and the Medical Board of California. The bill would require a pharmacist to complete a training program on the use of opioid antagonists prior to performing this procedure.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4052.01 is added to the Business and Professions Code, to read:

4052.01. (a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California.

(b) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.

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MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: SB 500
Author: Lieu
Bill Date: January 9, 2014, Amended
Subject: Medical Practice: Pain Management
Sponsor: Author

DESCRIPTION OF CURRENT LEGISLATION:

This bill would require the Medical Board of California (Board) to update the pain management guidelines every five years, beginning July 1, 2015. This bill would require the Board to convene a task force to develop and recommend the revised guidelines to the Board. This bill would allow the Task Force to consult with specified entities when developing the revisions to the pain management guidelines.

ANALYSIS

At the April 25, 2013 Enforcement Committee Meeting, the Committee established a Prescribing Task Force. This Task Force was convened to further define best practices related to prescribing controlled substances and to revisit the pain management guidelines to address the serious problem of inappropriate prescribing. The Task Force had its first meeting on September 23, 2013, and discussed corresponding responsibilities of physicians and pharmacists for prescribing and dispensing. The next Prescribing Task Force is set for February 19, 2014, and at this meeting the discussion will focus on revisions to the pain management guidelines.

This bill would require the Board to update the pain management guidelines every five years, beginning July 1, 2015. This bill would require the Board to convene a task force to develop and recommend the revised guidelines to the Board. Lastly, this bill would allow the Task Force to consult with the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Physicians, the American Cancer Society, a physician who treats or evaluates patients as part of the workers compensation system, other medical entities specializing in pain control therapies, and specialists in pharmacology and addiction medicine, when developing the revisions to the pain management guidelines.

This bill would codify work that the Board has already begun to address the important consumer protection issue of inappropriate prescribing. The Board has identified revising these guidelines as an important tool to help combat inappropriate prescribing. This bill will ensure that the pain management guidelines are revised, and then reviewed in a consistent, ongoing manner to provide appropriate guidance to physicians who are prescribing pain

medication. Board staff suggests the Board support this bill, as it furthers the Board's mission of consumer protection.

FISCAL: Minimal and absorbable fiscal, as a task force has already been convened and meetings are already planned to address this issue.

SUPPORT: None on file

OPPOSITION: None on file

POSITION: Recommendation: Support

AMENDED IN SENATE JANUARY 9, 2014

AMENDED IN SENATE JANUARY 6, 2014

SENATE BILL No. 500

Introduced by Senator Lieu

February 21, 2013

An act to amend Section 2241.6 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 500, as amended, Lieu. Medical practice: pain management.

Existing law establishes the Medical Board of California within the Department of Consumer Affairs. Existing law, among other things, required the board to develop standards before June 1, 2002, to ensure the competent review in cases concerning the management, including, but not limited to, the undertreatment, undermedication, and overmedication of a patient's pain.

This bill would require the board, on or before July 1, 2015, to update those standards. The bill would require the board to convene a task force to develop and recommend the updated standards to the board. The bill would also require the board to update those standards on or before July 1 each 5th year thereafter.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 2241.6 of the Business and Professions
2 Code is amended to read:

2241.6. (a) (1) The board shall develop standards before June 1, 2002, to ensure the competent review in cases concerning the management, including, but not limited to, the undertreatment, undermedication, and overmedication of a patient's pain.

(2) The ~~division~~ *board* may consult with entities such as the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Emergency Physicians, and any other medical entity specializing in pain control therapies to develop the standards utilizing, to the extent they are applicable, current authoritative clinical practice guidelines.

(b) The board shall update the standards adopted pursuant to subdivision (a) on or before July 1, 2015, and on or before July 1 each fifth year thereafter.

(c) The board shall convene a task force to develop and recommend the updated standards to the board. The task force, in developing the updated standards, ~~shall~~ *may* consult with the entities specified in paragraph (2) of subdivision (a), the American Cancer Society, *a physician who treats or evaluates patients as part of the workers' compensation system,* and specialists in pharmacology and addiction medicine.

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MBC TRACKER II BILLS
1/29/2014

BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 18	Pan	Individual Health Care Coverage	2-year	06/24/13
AB 357	Pan	California Healthy Child Advisory Task Force	2-year	01/16/14
AB 369	Pan	Continuity of Care	2-year	01/16/14
AB 395	Fox	Alcoholism and Drug Abuse Treatment Facilities	2-year	07/10/13
AB 467	Stone	Prescription Drugs: Collection and Distribution Program	2-year	01/07/14
AB 473	Ammiano	Medical Marijuana: State Regulation and Enforcement	2-year	05/24/13
AB 678	Gordon	Health Care Districts: Community Health Needs Assessment	2-year	04/15/13
AB 889	Frazier	Health Care Coverage: Prescription Drugs	2-year	05/02/13
AB 975	Wieckowski & Bonta	Health Facilities: Community Benefits	2-year	05/24/13
AB 1310	Brown	Medi-Cal: Pediatric Subacute Care	2-year	05/24/13
AB 1558	Hernandez	California Health Data Organization	Introduced	01/28/14
ACA 1	Donnelly	Administrative Regulations: Legislative Approval	2-year	12/03/12
ACA 5	Grove	Abortion: Parental Notification	2-year	01/07/14
SB 18	Hernandez	California Health Benefits Review Program	2-year	04/17/13
SB 22	Beall	Health Care Coverage: Mental Health Parity	2-year	07/02/13
SB 176	Galgiani	Administrative Procedures	2-year	08/07/13
SB 204	Corbett	Prescription Drugs: Labeling	2-year	06/27/13
SB 218	Yee	Healing Arts: Ca Traditional Chinese Medicine Traumatologist	2-year	08/05/13
SB 248	Wyland	Professional Corporations	2-year	
SB 270	Padilla	Underground Economy: Enforcement Actions	2-year	
SB 577	Pavley	Autism & Other Developmental Disabilities: Employment	2-year	01/06/14
SB 799	Calderon	Health Care Coverage: Colorectal Cancer: Testing & Screening	2-year	05/08/13
SB 830	Galgiani	Health Care: Health Facility Data	Introduced	01/06/14

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: January 23, 2014
ATTENTION: Members, Medical Board of California
SUBJECT: Legislative Proposal
STAFF CONTACT: Jennifer Simoes, Chief of Legislation

BACKGROUND

The Medical Board of California (Board) raised the issue of accelerated three-year and competency-based medical school programs as a new issue in its Sunset Report. A nationwide physician shortage is projected to reach 90,000+ physicians by the year 2020. Nearly half of that shortage is projected for primary care doctors (family physicians, pediatricians, and family practitioners). The federal Affordable Care Act (ACA) contains provisions to relieve the projected shortage of primary care professionals. Combined with the Prevention and Public Health Fund and the American Recovery and Reinvestment Act, the ACA will provide for the training, development and placement of more than 16,000 primary care providers, including physicians, over the next five years. A significant deterrent to becoming a physician is the substantial cost of medical education. At an estimated cost of $80,000 per year, a medical student can easily accrue a debt of up to $400,000 upon graduation.

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

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

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

There are also some California Medical School Programs that are proposing or considering competency-based tracks for students that excel and can progress at a faster rate than the standard four-year program.

There is a concern that some accelerated programs may not meet the requirements of Business and Professions Code Sections 2089 – 2091.2, and legislative changes are needed in order to accommodate changes in medical education and to license graduates from the accelerated curriculum programs.

Specifically:

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

RECOMMENDATION

Board staff has met with staff from the University of California (UC) Office of the President and discussed the need for legislation to accommodate the accelerated three-year and competency-based medical school programs. Board staff has drafted language that would allow for these programs, only if they are accredited by the Liaison Committee on Medical Education (LCME). Board staff has determined that applicants who graduate from an accredited LCME program meet the minimum medical education requirements. Board staff is requesting approval from the Board to co-sponsor legislation with the UC to allow for accelerated three-year and competency-based medical school programs, only if they are approved and accredited by LCME. Board staff recommends that legislation only be co-sponsored by the Board if the UC Office of the President is approved to co-sponsor the legislation.