# MEDICAL BOARD OF CALIFORNIA
**Executive Office**

**AGENDA ITEM 2**

Medical Errors Task Force
San Francisco Embassy Suites
250 Gateway Blvd.
So. San Francisco, CA 94080
July 24, 2008

## MINUTES

**Task Force Members Present:**
Frank Zerunyan, J.D., Chair
Steve Alexander
Reginald Low, M.D.
Mary Lynn Moran, M.D.
Gerrie Schipske, J.D., RNP

**Other Board Members Present:**
Barbara Yaroslavsky
Richard Fantozzi, M.D.
Gary Gitnick, M.D.
Hedy Chang

**Staff Present:**
Barb Johnston, Director
Kim Kirchmeyer, Deputy Director
Janie Cordray, Research Director
Renee Threadgill, Chief of Enforcement
Kurt Heppler, Legal Counsel, DCA
Linda Whitney, Chief of Legislation

**Members of the Audience:**
Tara Kittle, Blue Diamond Foundation
Elizabeth Banks, Pharm.D., CDPH, Ctr.for Healthcare Quality, Licensing & Certification
Lorie Rice
Phillip R. Hinderberger, NORCAL Sr. VP & Government Affairs Counsel

**Agenda Item 1 Call to Order**

The Medical Errors Task Force of the Medical Board of California was called to order by Chair Frank Zerunyan at 10:05 a.m.. A quorum was present, and due notice had been mailed to all interested parties.

**Agenda Item 2 Approval of the Minutes from the April 24, 2008 Meeting:**

Approval of the minutes of the April 24, 2008 meeting was postponed until the next Task Force meeting. Notice had been posted within 10 days, but as there was some debate regarding posting during business hours, counsel advised this postponement "in an abundance of caution."

**Agenda Item 4 Presentation of Current California Laws Relating to Medical Errors (SB 1301 & SB 1312 (Alquist)) by the Department of Public Health, Center for Healthcare Quality, Licensing and Certification Program – Elizabeth Banks, Pharm.D.**

Mr. Zerunyan said he was going to ask that agenda items number four and five be presented first, with number 3 last, so Janie Cordray could summarize the discussions and make recommendations at the close of the meeting.

Mr. Zerunyan introduced Dr. Elizabeth Banks, from the California Department of Public Health, Licensing and Certification Branch.

Dr. Banks gave a presentation on their Department's implementation of the Alquist legislation, SB 1301 and SB 1312, and the new requirements for adverse event reporting for hospitals and other facilities

As a result of the legislation, the new requirements became effective on July 1, 2007. She said she would give a background of the legislation, the facilities affected, the types of events covered, and the time frames for reporting, penalties for failure to report, and the Department's responsibility for implementation.

SB 1301 was introduced due to a heightened awareness of the problem of preventable medical errors. The new requirements are intended to promote greater public safety by increasing oversight and disclosure of errors to the public. The law, added to the Health and Safety Codes, applies to general acute care hospitals, psychiatric hospitals, and specialty hospitals. Health & Safety Code Section 1279.1 defines 28 adverse events that should never occur in hospitals and specifies those events should be reported to the Department.

The first 27 events were published in 2002 by the National Quality Forum. Adverse events include surgical events, product or device events, patient protection events, care management events, environmental events, criminal events, and another event that she would explain by reading a definition: "An adverse event or a series of serious adverse events that cause a death or serious disability of a patient, personnel, or visitor." This definition has caused some controversy. She explained "serious disability" is defined where as "visitor" is not.

"Surgical event," she explained, included wrong site surgery, wrong patient, wrong procedure, retention of a foreign object, or death after induction of anesthesia. "Product events" are defined

as disability from a contaminated drug, device, or embolism. "Protection" is an infant given to the wrong person or patient suicide. "Care management" is defined as death or serious disability from a medication error, ulcers, and so forth. "Environmental" events are defined as death or serious disability from the use of restraints, electric shock, or death associated with fall. "Criminal" events include impersonation of a health care professional, as well as others.

Dr. Banks explained the definition of "serious disability" was "physical or mental impairment that substantially limits one or more of the major life activities in an individual or the loss of bodily function if the impairment or loss lasts more than seven days or is still present at the time of discharge."

The law requires these events be reported within five days, or within 24 hours if the health or safety of patients or visitors is threatened. In response from reports from facilities, Section 1279.2 of the Health & Safety Code requires the department to make an on-site inspection or investigation within 48 hours or 2 business days, whichever is greater, if the report is for an event that indicates there is an ongoing threat or imminent danger or death or serious bodily harm. If, as part of the investigation, the department finds the event was not reported in a timely manner, fines can be assessed. The amount of the penalty is 100 dollars for each day the event was not reported. Hospitals may challenge the penalty. As of July 2008, 102 penalties have been assessed.

H&S Code section 1239.2 addresses inspection requirements and the authority of the Department to assess civil penalties. For the reporting period of July 1, 2007 through June 30, 2008, 1225 adverse events were reported statewide. Of those reported, 607 were related to stage 3 or 4 pressure ulcers. Surgical events ranked second highest, and reports included 172 reports of retention of a foreign object, 40 deaths after anesthesia induction, and only 34 medication errors.

One challenge to the Department is understanding how facilities perceive and report events. As an example, defining events and other factors or terms such as "visitor." If someone is visiting a staff member, is he or she a "visitor?"

By January 1, 2009, CDPH must make information about substantiated reports and inspections readily available to the public. By January 2015, the information must be on the Department's website.

Dr. Banks said work has already been performed to reduce medication errors, including work performed by the National Quality Forum and the Medications Error Task Force. As part of a fair and just culture, it is now recognized that most errors occur secondary to system design flaws and drifts in behavior, rather than gross incompetence or negligence on the part of an individual. As part of the Department's commitment to quality, they actively pursue opportunities to discuss and disseminate patient safety information to partners in the state.

Dr. Low remarked the category "death after induction of anesthesia" should not imply there was an error, as some patients' diseases or conditions would account for the event. He asked how the

department separates those events that are not a result of error. Dr. Banks stated such an event would not necessarily be an error, but it is a reportable adverse event that must be investigated.

Dr. Low stated he thought that a $100 per day fine was insufficient for hospitals, and it would be difficult to audit underreporting. Dr. Banks said she was unsure of the deterrent or incentive effect of the amount of fine, but it is the law. Dr. Low said he thought that 1,200 reported errors seemed to be an extremely small amount, and the system, while it does track some events, is not capturing the full picture of the problems. Dr. Banks said she was in complete agreement, however, the fines are established in law. At $100 fine per day, however, if the Department discovers as part of an investigation that an event was not reported for five years, the fine could be substantial.

Gerrie Schipske thanked Dr. Banks for her presentation, and said as Dr. Low had suggested, adverse events are not only errors, and therefore she thought the terminology should be changed to speak of patient protection. The shift in vocabulary has already taken place at the national level, recognizing that many adverse events are unrelated to mistakes or errors. She said as the Board continues to look at the subject, the terminology should shift to patient safety. Dr. Banks said it was not her intention to imply events were a result of medical error, but reportable events are investigated to determine if actions should be taken to promote greater safety. The law speaks only of events, not errors. As stated before, most events are secondary to system design flaws, not individuals.

Mr. Zerunyan said he appreciated the comments of his colleagues. He said he was interested in the "just culture" and the notion of having a non-punitive approach. He said there are a number of programs utilizing this approach, such as the state and federal reporting programs, while the nature of the Board's actions are by definition punitive, and therefore the terminology is very different.

Tara Kittle, a consumer, said that she was the CEO of the Blue Diamond Foundation, an organization she founded to address the lack of access to medical care and lack of physician control of medical care. She said the key element of the speaker's presentation was that most errors are not errors of an individual, but a system flaw. It is the larger social forces that cause the errors. For that reason, in her opinion, the Task Force should focus its efforts on those problems.

**Agenda Item 5 Presentation on SCR 49 Medication Errors Panel – Lorie Rice**

Lorie Rice said as well as being a former Medical Board member, she served for eight years as the Executive Director of the Pharmacy Board. She said her recommendations to the Task Force were a result of her experience as a Board member and a staff person responsible for implementing programs within governmental limitations. Ms. Rice said the SCR 49 panel was formed to address medication errors. The panel published a number of recommendations, and encouraged the members to review them.

The final report of the panel was entitled "Prescription for Improving Patient Safety - Addressing Medication Errors." The panel, on the initiation of the Senate, worked for two years to develop the recommendations.

Ms. Rice said she had reviewed the Task Force minutes, and noted that Ms. Schipske had said a large portion of medical errors are medication errors. Ms. Rice said she agreed, and therefore would be addressing medication errors.

Ms. Rice said she would share with the Task Force some observations and recommendations. Her first recommendation would be to develop some definitions of topics or categories that the Task Force will attempt to address. She would recommend the members come to agreement on the goals so that the work can be efficiently focused.

The Medications Errors Panel on which she served, discussed at length the direction, goals, and feasibility of their work. For that reason, she would encourage the membership to review the panel's recommendations so that they not reinvent the wheel. Their panel had at least 25 different speakers address them, and the educational element of their work was an extreme help to their members to focus on workable solutions. The Medical Board can certainly call its own committee hearings, but there are many organizations experienced and already working on the problem that can assist and supply information. She would encourage the Task Force to look at what is already developed.

As a past Board member, Ms. Rice said she understood there are a number of competing interests for the Board, and the members must decide on the level of resources the Board wants to dedicate to any new activity. It must decide how much money to expend, what staff resources to use, and what it will leave behind for the use of the resources. She recommended that anything the Board decides to do, they should try to make it time specific, and, if possible, make short term goals that can be evaluated. She also said it is important that the full board is fully supportive of anything a committee wishes to initiate.

The report of the panel on medication errors made five recommendations. She said two or three of the recommendations are well suited for the Medical Board's attention. One was communication improvements, with an emphasis on the quality and accuracy of communication between prescribers, pharmacists and patients. The recommendation was specific in how to accomplish it, and she would encourage the members to review them, and, after review, endorse them. One of the recommendations she thought was of particular importance is the requirement for all prescriptions to have the indication on the prescription and the container label.

She said the panel made a number of recommendations relating to legibility of prescriptions, and it encouraged the use of e-prescribing. Ms. Rice said, in her opinion, eventually e-prescribing will be embraced, but she was unsure if the Medical Board had ever taken a position on encouraging its use. The second section of the report is on consumer education.

Ms. Rice said she thought the initiatives were appropriate for the Medical Board to consider and support. There are already organizations working on them, and the Board could support their efforts without great resource expenditure.

The Board has a vast library of information in its disciplinary and complaint material. In the Board newsletter, everyone wants to see who's been disciplined and for what. The Board has a unique opportunity to educate physicians and patients by sharing more information about what mistakes are happening, as everyone can learn from the mistakes of others. Perhaps a few cases a month should be spotlighted, outlining the error made, and asking the audience how it could have been avoided. That approach could get the community thinking about certain types of errors, as most are extremely common, occurring over and over again.

Ms. Rice said she would answer questions, and would be happy to help the Board in their efforts. Dr. Low said he thought technology could play an important role in addressing medical errors, and supports e-prescribing. He asked Ms. Rice what prevents wider use of electronic prescribing. Ms. Rice said the panel's report widely covered that subject. There are two major reasons for the reluctance of physicians to move to e-prescribing. First, there is a fear of technology. Secondly, there is substantial cost. In her opinion, many physicians think that e-prescribing is a good idea, but they are waiting for the third-generation technology before they invest in it. Future systems may not only cover e-prescribing, but integrate patient and medication records.

Dr. Low said electronic records are now being adopted in hospitals, and those that have implemented ordering through electronic records systems have reduced medication errors. He asked Ms. Rice how the Board can promote more hospitals to transition to electronic medical records systems. She said the panel's work did not specifically speak to hospitals. She said their work primarily focused on individuals in private practice and outside hospital settings where many of the medications occur. There are actually more checks and balances in hospitals than in physician's offices and corner pharmacies. There are often no nurses involved, or anyone else who might discover the error and intervene. She said she thought prescription errors should be viewed in community practice as well as in hospitals.

Mr. Zerunyan said the topic of errors is important, and there is a correlation to consumer protection. The issue, however, as he sees it, is whether there is an unoccupied space into which the Board should step. From his perspective, there are many organizations addressing errors, and asked Ms Rice if she was familiar with the VA Center for Patient Safety.

Ms. Rice responded she was not familiar with that particular organization, however, she agreed with his statement that there are hundreds of organizations working on the medical and medication errors issues. From professional organizations, consumer organizations, professional associations, as well as academia, all are addressing the problem. For that reason, it is her opinion the Board should work with others, either by endorsing their efforts or by forming partnerships, as well as educating the public and professions about the programs. In addition, Ms. Rice said, there are a number of continuing education programs of value, and the Board should encourage participation.

Dr. Banks said the VA Center for Excellence Top Flight has an excellent and extensive database that is a wonderful source of information. In addition, the ISMP, the Institute of Safe Medicine Practice, is also a great source of information. Ms. Rice agreed, and added the Federal Government has an excellent database for medication errors.

Ms. Schipske said for future meetings, she would like to have a report on the Federal legislation and their initiatives. Dr. Banks added the National Safety Goals are on the ISMP website.

Tara Kittle said she was troubled by the statements made that others were handling the problem. She said it could be said for everything, but it is the role of the Medical Board to become involved in the solution to the problems. The Board, because of its relationship to disciplining physicians, has a particularly intimate involvement with medical errors and therefore can provide insight and direction to the profession in a manner in which no other agency in the state can. The Board has a responsibility to address medical errors to guide legislators and the public.

**Agenda Item 3** **Overview – Who is Addressing Medical Errors and How? – Janie Cordray**

**Agenda Item 6** **Discussion of Task Force Direction**

Janie Cordray directed the members' attention to the written report in their meeting materials. She said the report entitled "who is addressing medical errors?" provided a summary of a number of organizations and programs addressing medical errors. As Ms. Rice had previously stated, there are numerous organizations dealing with the problem. Some programs work to address the problem of medication errors, others work to identify systems problems within institutions, some promote physician-patient or institution-patient communication, a few are addressing institutional infections, while others grade facilities and practitioners for consumers.

Ms. Cordray said most programs are analyzing data gathered on errors and events to develop systems, or safety nets, to prevent future problems. The data gathered from the new Federal System will likely help their efforts, and the event reporting in California that Dr. Banks presented will also be of great assistance.

Ms. Cordray said Mr. Zerunyan had asked her to wrap-up the day's discussions by summarizing the Board's role, and to provide some recommendations about what practically could be achieved within the Board's resources.

She said, in relation to medical errors, the Board's strategic plan stated, "Create a plan to assist in addressing medical errors as appropriate to the Board's Mission and resources."
At the previous Task Force meeting, the members adopted the working statement, "To examine the Board's role in promoting patient safety, through developing or participating in systems that encourage and assist physicians in addressing medical errors consistent with the Board's Mission and resources."

Ms. Cordray stated she had reviewed the last meeting's minutes, and paid particular attention to comments made by Board members, both on and off the Task Force, as well as those made by consumers providing public comment. Both members of the board and the public stated they wanted the Board's resources used to do its job, which is to protect consumers from bad doctors. The public particularly said they wanted transparency to enable them to make informed choices.

Transparency is evident in the programs summarized by Ms. Rice and Dr. Banks, perhaps more importantly, education and communication is the key to their success and failure.

Ms. Cordray said an independent, comprehensive program to address medical errors of physicians throughout the state is beyond the Board's resources, and would duplicate the many already mandated reporting programs. Healthcare professionals are governed by a number of diverse boards who also do not have the resources. Regulatory boards, however, are not in the position to know what is happening in doctors' offices or hospitals on a daily basis, and are informed when things go wrong. Through the investigative process, experts inform Boards whether or not an event was a result of grossly negligent, incompetent, or dishonest conduct.

If a regulatory board learns of a system error, it is likely already being addressed, either by the facility, or by CDPH Licensing & Certification Branch. The Board regularly sends Licensing & Certification information when investigations find facility problems, and they regularly inform the Board when their investigations identify physician problems. No board has the necessary staff or expertise to design systems or system improvements.

Ms. Cordray said the Board can act as a conduit of information and as an educator. It can tell consumers of the Board's existence and encourage them to utilize its complaint process and educational materials. Information can be shared with licensees about frequent problems and programs that have been developed to prevent them. The Board can assist patient safety programs by encouraging physician participation. In addition, the Board can report on the activities of the Licensing & Certification Branch or the Medical Errors Panel, or any other program with useful information.

Ms. Cordray said the following options should be considered by the members:

- Continuation of member education. There are a number of organizations contained in the report that have indicated they are anxious to speak to the Board about their programs. Ms. Cordray said she would schedule speakers at future task force meetings if requested. The Board can partner with organizations through endorsement, publicizing their information, or encouraging participation, as Ms. Rice had recommended.
- Education of the members of the full board. Although speakers can be scheduled for the task force meetings, many of the groups have information that is of interest to the entire board membership. In some cases it might be appropriate to schedule speakers for Board meetings.
- Utilization of the Education Committee. If it is the desire of the Task Force and the Board to begin to act as a conduit of information and educator, these subjects might be

better addressed by the Education Committee. The large circulation of the Board's newsletter, as well as its website could be a great source of information for licensees. The public education efforts of the committee could assist with getting useful information to the public.

Ms. Cordray stated in her opinion, the greatest role the Board could play is that of a conduit of information. As many of the initiatives, including the new Federal reporting and the state facility event reporting systems, progress, there will be greater and more useful information to share with the profession and the public. In addition, as Ms. Rice had said, the Board has a wealth of information in its complaint and investigation files, and the information should be gathered and shared in a manner to educate and inform.

Ms. Cordray said she was making no recommendations to the members, only options to consider. If agreeable, staff can continue to share information to educate members, and continue to communicate with the various organizations that are working on the problems surrounding medical errors.

Ms. Schipske said she had noticed the Cal Attorney magazine, the publication that reports on actions against attorneys, has substantially more detailed information about the offense or offenses causing the disciplinary action than the Board's newsletter. Instead of just the code section of the violation, it actually details the offenses. She asked if staff could come back with a recommendation, along with legal counsel, about what information could be added to the published report on discipline. She would like more of a description of what the physician actually did. Publishing only the section of law violated is not very informative.

In addition, Ms. Schipske said she would like to hear from the malpractice carriers. The legal malpractice carriers offer education courses, and to promote enrollment, they offer reduced premium rates for taking them. She said in her opinion, consumer information is critical.

Mr. Zerunyan said he agreed with Ms. Schipske's comments, and asked if there were any comments from the public.

Tara Kittle said the gathering of information from complaint and investigation files was an excellent idea. If the Board would think of medical errors like car accidents, the Board has a front row seat to the collisions and knows where stop signs should be placed. For that reason, the Board is in the position to provide the best guidance for prevention. The Board could play a significant role in finding preventative measures by identifying patterns of errors and events. The information in the Board's possession is like no other agencies', and if shared, could be incredibly helpful to consumers and the profession.

Mr. Zerunyan asked the members if they had any further suggestions, and asked if there was anything specific they wanted him to report to the Board at the meeting the next day. He said he would report factually what occurred at the meeting, but asked if there was anything specific they would like added to the report.

Ms. Schipske said she would like to receive some guidance from staff and counsel on the possibility of expanding the disciplinary information in the newsletter. Specifically, she would like to know what information could be disclosed legally on the website and the newsletter. At some point, she would also like to hear a presentation on the status of the Federal error reporting system. In addition, she said she would like to hear a presentation from malpractice carriers.

Dr. Moran said she would like to have more information on other programs upon which the Board could assist in providing information and educational opportunities.

Dr. Low said he would like to become more focused on what the Board can actually achieve and agreed the staff report gave the members some ideas. He said he thought the Board should focus on the things that can be accomplished by the Board.

Mr. Zerunyan said he agreed with everyone's suggestions, and thought that having the malpractice carriers, along with other programs, such as 5 Million Lives, as well as hospital risk managers, present information to the Board would be helpful. As Ms. Cordray had suggested, the Board can be a conduit of information to the public and profession on the information gathered. Overall, he would like the Board to be helpful and work within its means.

Ms. Kittle said there was a discussion at the last meeting about defining "medical error." She said she went online and the definition she thought was best was "a medical action or inaction that results in more harm than benefit to the receiver." This definition would cover surgery errors and incidents where the patient is sent home undiagnosed or misdiagnosed. She thinks that definition would provide an adequate framework for the work of the members. Ms. Kittle provided an informational packet to the members.

As there were no others that wished to speak, Mr. Zerunyan thanked the members and audience for their participation and adjourned the meeting at approximately 11:30 a.m..