



MEDICAL BOARD OF CALIFORNIA
Executive Office



AGENDA ITEM 2

**Medical Errors Task Force
Sacramento Convention Center
1400 J Street, Room 203
Sacramento, CA**

April 24, 2008

MINUTES

Agenda Item 1 Call to Order/Roll Call

The Medical Errors Task Force was called to order by Chair Cesar Aristeiguieta, M.D., on April 24, 2008 at 8:30 am. Janie Cordray, the Task Force Committee staff person, read the roll call.

Members Present:

Cesar Aristeiguieta, Chair
Steve Alexander
Reginald Low, M.D.
Mary Lynn Moran, M.D.
Gerrie Schipske, R.N.P., J.D.

Members Absent: None

Agenda Item 2 Approval of Minutes from January 31, 2008 Meeting

Dr. Aristeiguieta called for the approval of the January 31, 2008 meeting minutes.

It was M/S/C (Yaroslavsky/Moran) to approve the minutes from the January 31, 2008 meeting.

Agenda Item 4 – Discussion of Task Force Mission Statement:

Dr. Aristeiguieta asked the members to discuss item number 4 on the agenda. He directed the members' attention to the briefing memo from Janie Cordray regarding the working statement for this committee. The members had adopted a statement at the last meeting, indicating the task force should examine the Board's roll to determine if it could provide greater public protection by becoming involved in initiatives to reduce medical errors or other ways it might provide assistance with this issue.

Dr. Aristeiguieta asked the members for their comments.

Steve Alexander recommended adding "consistent" rather than "is appropriate to" in the phrase so it read "consistent with the Board's mission and resources. He said that the Board may actually develop some things, or participate in what others are doing, and all must be consistent with the Board's mission and resources.

Dr. Aristeiguieta asked Mr. Alexander to restate the entire statement. Mr. Alexander said, "To examine the Board's role in promoting patient safety, through developing or participating in systems that encourage and assist physicians in identifying and remedying medical errors, consistent with the Board's Mission and resources."

Mr. Alexander was made a motion to adopt the statement.

Dr. Aristeiguieta asked for comments on the motion.

Dr. Mary Moran stated that the statement was solid and did not overreach.

Dr. Aristeiguieta asked Mr. Alexander to entertain a friendly amendment. He said his only concern was about the word "remedying." He said the Board could certainly help identify problems, but to find remedies may be unrealistic.

Dr. Mary Moran suggested eliminating "identifying and remedying" replacing them with "addressing." Mr. Alexander agreed.

Dr. Aristeiguieta restated the mission 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."

Motion carried.

Mr. Alexander asked the statement be included on all future Task Force agendas.

Agenda Item # 3 – Discussion of the Board's Potential Role in the Prevention of Medical Errors:

Dr. Aristeiguieta stated the problem of medical errors is broad and complex, and the Board has no definition of what it may consider to be a medical error. He recommended on this meeting and future meetings, the members would engage in larger discussions. He said he wanted to be clear that nothing would be decided and no action would be taken. The members have not yet heard from or had any presentations from groups on any of the issues, which he hoped would be scheduled for future meetings.

He stated the issue is a two-part problem. The first problem was issues he had seen in two disciplinary cases, where there was a medical error that resulted in discipline under what is called a "Captain of the Ship Doctrine." Because a physician was in charge of the care, the physician was disciplined, but may or may not have had any part in the medical error that led to that discipline. He said staff should identify such cases and bring to the members a report on what processes might avoid such events.

Dr. Aristeiguieta stated the second part was broader, which is to determine how the Board may deal with the grander scheme of medical errors. He stated there are a variety of entities outside of Board, which are carrying on a variety of programs, including bar-coding pharmaceuticals, changing work habits within hospitals, or reporting systems, such as the federal government's implementation of "no fault, non punitive" system of reporting.

Dr. Moran asked where such programs are being implemented. Dr. Aristeiguieta said Janie Cordray would give a short briefing on the subject later in the meeting. He explained the Federal Government was developing a nationwide program that would establish a volunteer data base of reporting of medical errors in which the subscribers then have access to the data, with identifiers removed, for the purpose of education, training, and system improvement.

Dr. Moran asked if the system was outside of the state medical boards' disciplinary systems.

Dr. Aristeiguieta said it was and physicians, medical groups, hospitals, and others would voluntarily report to the data base. The firewall in that system would prevent licensing agents or others from accessing the information, other than for the purposes of education and system improvement.

Dr. Aristeiguieta said there have been questions posed about the bullet points on the agenda. He wanted to make clear the points were for discussion only. He asked if Ms. Cordray had any comments.

Ms. Cordray said clarified some of the points made to ensure there was no misunderstanding. She said the Medical Board did not discipline doctors for medical errors, but instead, disciplined physicians for gross negligence, repeated negligent acts, incompetence, or dishonesty. A single report of an error would probably not result in discipline unless it was an extreme departure from the standard of care, the legal element necessary for disciplinary action. If a physician makes a mistake that is not grossly negligent or incompetent, but changes records to cover-up the mistake or behaves in a way to obstruct justice, or acts dishonestly so that problems cannot be remedied, that is the conduct that brings about disciplinary action.

Ms. Cordray said the annual statistics of Board actions demonstrates that physicians are not disciplined for simple medical errors, and places the actions in the proper perspective. The Board receives 7,500 complaints every year, and about 6,000 of those are jurisdictional. Formal investigations are conducted on 1,500 of them, and of those, only about 300 go to the Attorney General's Office for the filing of formal accusations.

Ms. Cordray stated the no-fault reporting system Dr. Aristeiguieta spoke of was the Patient

Safety and Quality Improvement Act of 2005. It is a no-fault error reporting system that will be used for education and system improvement. While the reporter is immune, the act of reporting the error does not immunize the reporter from disciplinary action by licensing boards or others. The information is specifically shielded from regulators, so any disciplinary case will have to be developed from an independent investigation and other sources of evidence.

The implementation of the system is reliant upon Patient Safety Organizations (PSOs) that will act as the repository of the error reports. The Health & Human Services has been slow to promulgate regulations, which has slowed the implementation of the Act. The regulations have now been promulgated and the public comment period has ended. It is expected the system will be in place later in 2008.

Ms. Cordray stated the scope of medical errors is enormous, and it is not confined to physician error, but involves nurses, pharmacists, allied health professionals, facilities, pharmaceutical companies, and others. If the Act creates a database that is fully utilized, the PSOs will compile the data in regional areas, analyze it, and will be able to determine frequency. That is important, in that if the error only occurs once, it is probably not significant. If it is frequent, the problem will be analyzed and then publicized, so that systems can be developed for prevention.

Ms. Cordray said there are many groups involved in the project and will become recognized PSOs. She reminded the members she had sent a package of information to them about a number of patient safety initiatives. The most visible program is the Five Million Lives Campaign, which started out as the One Hundred Thousand Lives Campaign. There are many others, however, and a number of them have offered to make presentations to the Board.

Ms. Cordray suggested the members educate themselves about all of the various programs in existence to determine if the Board can assist, rather than develop their own program. There are many experts that have offered to make presentations. If the members are agreeable, speakers from the various groups could be scheduled to speak at future meetings.

Dr. Moran said the federal reporting system was interesting, but outside the purview and mission of the Board. She would caution the Board identifying with any "no-fault" system. The Board has in the past, and must in the future, strive for transparency. She would caution against any state "no-fault" reporting system.

Ms. Cordray said the Federal no-fault system, just like the FAA system, does not immunize those that made errors from disciplinary action. It provides immunity for reporting, much like we have for Business & Professions Code Section 805 reporting immunity in California. A reporter cannot be held responsible, but it does not mean the person responsible for the error is immune from other action. The Federal reporting system in no way interferes with what the states do. The states will retain their own reporting requirements and disciplinary processes.

Dr. Moran stated her concern was the failure of reporting by hospitals. Under current state laws, hospitals and insurance companies are not reporting as often as they should, and that should be a focus of the Board.

Dr. Aristeiguieta stated he would like to invite other state regulators that deal with hospitals and other licensees, to discuss how data can be better shared. If one agency finds a problem, a bridge must be built between agencies so information can be shared. He said he would like the Board to develop working relationships to allow all to share information with the hospitals, or the quality assurance organizations, or whoever the appropriate recipient of information where it might be helpful.

Dr. Moran asked what current fine is for failure to report under Business & Professions Code Section 805. Ms. Cordray responded fines could be as great as \$100,000.

Kimberly Kirchmeyer clarified the fine was up to \$50,000 for failure to report, and \$100,000 for a violation that was willful.

Ms. Moran asked how often fines are levied. Ms. Cordray responded that while fines have been levied, it is difficult to know the scope of the problem. If the Board knows a report should have been filed and was not, a fine will be levied. The Board, however, cannot levy a fine if they do not know about the action. Ms. Cordray explained the Board has contracted with Lumetra to perform a study on peer review, and the work should be completed in July. The study may provide some insight into the reporting problem.

Dr. Moran asked if the Board could compel random or regular audits. Ms. Cordray responded the Board did not have that authority, and peer review records, for the most part, are not discoverable. Kurt Heppler, legal counsel, said there was a specific statutory provision preventing their disclosure.

Ms. Kirchmeyer explained there are other state reporting programs that are underway other than the Business & Professions Code Section 800 series of reports. There is new legislation requiring hospitals and other facilities to report events to the Department of Health Licensing and Certification Branch. The law also provides for greater fines for the events, and for failing to report.

Dr. Low asked if the group had any definition for the errors about which they were concerned – whether it should be wrong site surgery, errors in orders, or errors in prescribing. He said the issue of errors is so broad the members must define them in order to place their discussions in the right context.

Dr. Aristeiguieta said it would be part of the challenge for the group, and the members need a definition to move forward. Ms. Cordray had spoke about errors and what they are not, e.g. negligence, incompetence, recordkeeping or illegal activities, and the role of the Board is to protect the public from licensees when they engage in those types of actions or activities. He said a medical error is a systems error, and that is what the IOM said in their report. The question for the members is, “how does it work from there?” If it is not an individual making an error, it is a system that was not in place to catch that error when it occurred. In “To Err is Human,” there is a certain baseline amount of medical mistakes that will happen on a regular basis. The Board should explore what role or action it can take to encourage the systems to be developed to catch those errors before patients are harmed.

Dr. Aristeiguieta said the Task Force should hold a half-day session and invite experts. Staff can counsel them on the most appropriate dates and experts.

Dr. Low said it would be very difficult for the members to move forward without deciding what medical errors should be addressed.

Dr. Aristeiguieta said that the members needed to hear from the experts. After educating the membership, they will have a clearer vision as to which types of errors are appropriate for the Board to address.

Steve Alexander said the Board's role as a disciplinary/regulatory board potentially contributes to the "under grounding" of medical errors, depending on how they are defined, and therefore, potentially contributes to more patient harm rather than less. The challenge is to develop some criteria for solutions that would enhance public protection. The public has a role in the process, as well. He said he agreed the members need to hear from other entities before starting any development of programs or systems. The task force should prioritize solutions in which the board could engage.

Mr. Alexander said the members should define medical errors, develop a problem statement that will look at criteria for solutions, potential solutions with priorities, and identify the solutions to be pursued. He said the subject of medical errors was a huge universe until the group had a definition. He said it might be helpful to discuss what the members thought, and determine if the group could reach some consensus.

Dr. Low said a definition was needed early in their discussions, although there was probably not sufficient time to decide at the meeting. He said everyone probably held some biases and the group would benefit from having some input from others. After a half-day session of hearing from experts, the last hour should be devoted to deliberations to narrow down their focus. The speakers should be asked to give some guidance about their definition of errors. The goal of that meeting should be to establish a working definition.

Gerrie Schipske said the group would have better directions after hearing from speakers on the national patient safety initiative. After looking at the last meeting's minutes, she said she was concerned about focusing and calling the problem "medical errors." If what consumer protection agencies are trying to accomplish is how to best make healthcare settings safer for patients, most focus on patient safety rather than errors. Most initiatives do not focus on individuals, but systems. The value of hearing from others is to find out what conditions exist and what things cause unsafe conditions for patients. As had been pointed out previously, medical errors do not just involve physicians. She said in addressing problems, the top goal should be patient safety, involving education and other initiatives to promote safe practices. While the Board is a disciplinary body, the goal should focus on patient safety.

Dr. Aristeiguieta said the next step of the group should be to plan a half-day session to hear from speakers.

Public Comment:

Dr. John Keats, representing the California Patient Safety Action Coalition (CAPSAC). He stated his organization is a newly formed group of over 20 stakeholders in medicine in California, including large hospital systems such as Kaiser, Sutter, Catholic Healthcare West, California Medical Association, California Association of Physician Groups, Department of Managed Healthcare. They were formed to establish a fair and just culture within the medical community in California, starting with the hospitals. They are working with David Marks who has spearheaded similar statewide patient safety coalitions in other states, particularly Massachusetts and Minnesota, both of which have very robust medical error reporting systems and systems to disseminate the knowledge gained.

In the medical error literature, he added, there are clear answers to the many of the things discussed at the meeting, and it may not be necessary for the Board to reinvent the wheel. California has a statewide patient safety action coalition that is coming together, and Dr. Keats said he specifically came to the meeting to ask the Board's support in the efforts. They are holding a statewide convention of all stakeholders on July 11th in Newport Beach and invited members of the Medical Board and staff to attend this meeting to learn more about this effort. They are trying to establish a reporting culture and a learning culture within medicine in California.

Mr. Alexander asked Dr. Keats how many stakeholders were included in their program. Dr. Keats responded there were over twenty, and he would leave a copy of their charter, along with a fact sheet, with staff.

Mr. Alexander asked if there were any consumer groups involved. Dr. Keats answered SAFER and some other consumer groups, as well as medical malpractice carriers were involved.

Julie D'Angelo Fellmeth, Center for Public Interest Law, stated she had been at the first meeting of the task force. She said she was concerned about the mention of developing a no-fault confidential reporting system for medical errors. She agreed with the members that they had not yet defined "medical error."

Ms. D'Angelo Fellmeth said in her view, an error equals negligence, and if a doctor commits negligence, he or she may be subject to discipline, if it is repeated or if it is gross negligence. She said she didn't understand how these errors could be diverted into a no-fault, confidential program. If the Board does not discipline doctors who commit repeated or gross negligence no one else will.

Ms. D'Angelo Fellmeth handed the members an excerpt from their Strategic Plan, and noted the only thing that mentioned medical errors contemplated an educational program, not a no-fault confidential reporting system.

Ms. D'Angelo Fellmeth said she is not sure that there is a role for the Board in reducing medical errors, other than to discipline doctors who commit them repeatedly and egregiously. The Board

is the only body that can take disciplinary action against doctors. She cautioned the members to step back, reexamine their mission and strategic plan, and move more in the direction of education and interaction with the facilities to warn them of systemic problems that may result in physician discipline.

Tina Manasian said she was a victim of a participant in a no-fault confidential program that the Board housed for 27 years. She said the reason she was injured was because of the confidentiality of the diversion program. She said patients do not want or expect confidential programs from government regulators, they want transparency and accountability. If the Board continues on this path they are tempting legislators to completely dismantle the Medical Board for gross negligence of their duties to the public. She added, patients need is a transparent system of public discipline for doctors who commit repeated or serious error or injury to patients, not a confidential reporting program.

Dr. Aristeiguieta clarified the Board has not considered any one action at the exclusivity of any others relating to medical errors. The bullet points on the agenda were for discussion only. There is no proposal on the table to consider a no-fault reporting system

Dr. Gary Gitnick, Medical Board member representing himself, said but he opposed medical errors, but abhorred, even in concept, the notion of a no-fault, confidential reporting system.

Dr. Gitnick said the Board's mission is to license, regulate, and to discipline; albeit, for the benefit of the citizens of California. He said he fully supported the concept of finding ways of avoiding medical errors, but without hiding errors and without protecting those who perpetrate those errors.

Dr. Gitnick said there would be four elements needed for the Board in order to move in that direction:

- 1) Change in Law: Legislation would be needed to change the mandated mission if the Board desires to go into these areas for the good of the public;
- 2) Resources: The Board would need legislation for sufficient resources, so it can, at the minimum, go forward with the current mission, which the Board is not fulfilling;
- 3) Transparency: In no situation can the Medical Board, a committee of the Board, or an offshoot of the Medical Board participate in anything in secrecy. The public has the right to know, and the Board should not be a mechanism by which the public is prevented from knowing all;
- 4) Better Enforcement: The Board must fulfill its enforcement role. The *LA Times* article, right or wrong, whether it is based on a proper or improper interpretation of the data, is true in many areas. The Board must find a way of doing a better job of enforcement. It is losing enforcers and investigators. There is difficulty with the Department of Justice prosecuting many of the cases. The Board needs to get that done.

Dr. Gitnick noted that the task force has discussed the FAA reporting program. He said the confidential program that the FAA utilizes is only part of a much bigger system of regulation. Commercial pilots are subject to random urine testing. Pilots cannot fly commercial carriers if they are over 65. Should physicians be subject to random urine testing and mandatory

retirement? He said it is appropriate and possible for a guild, a union, a non-profit organization to promise confidentiality within the law, and to strive to eliminate medical errors. A State agency, however, cannot participate in any program that would be a no-fault, confidential reporting system. In closing, he said that he assured the members of his support of the concept of the Board striving to find a way to eliminate medical errors. The Board, however, cannot allow anyone to avoid responsibility and accountability, and cannot do it until there are sufficient resources.

Frank Zerunyan, a Medical Board member, speaking as a member of the public, said he is guided by the Board's mission, which is public protection. As had been discussed, the more the Board dilutes its resources, the less effective it will become in its primary mission.

Mr. Zerunyan said that he had five specific questions or points for the task force:

- 1) Is the role in prevention of medical errors consistent with the Board's mission?
- 2) Does that role place an affirmative, legal duty on the Board?
- 3) What is a medical error? The definitions for the Board are contained in California law, the Medical Practice Act, case law, which defines them for torts and the administrative arena. The Board has no room in it to create any kind of confusion for the public, the legal profession, or the medical profession.
- 4) What if whatever is undertaken does not reduce the medical errors? Is the Board then responsible for not reducing medical errors, as a result of a potential affirmative duty that it may have assumed?
- 5) No-fault or confidential programs have been a struggle for the Board for a very, very long time, with respect to the main mission of the Board of public protection. The diversion program was recently abolished, which fell in this arena. Those words, "no-fault" or "confidential," do not belong in the Board's Dictionary. The Board must strive for transparency and accountability.

Tara Lee Kittle said she was grateful for the Task Force's existence, and looked forward to the impact it could have on helping protect the public from medical errors. Helping to understand and get to the root of why medical errors occur seems exactly consistent within the mission. In regards to resources, she noted that on the agenda for the main quarterly board meeting there is a fee reduction for approval to offset the elimination of diversion program. She said she wondered why the Board would consider cutting fees, when those resources should be used towards solving problems

Ms. Kittle said she had brought an article on e-mail for doctors and it underscores an area that could help reduce medical errors -- compensating physicians for the work that they do so they may get paid for phone calls, for research, and for e-mails. She said by paying for the work and time to think, this would directly help reduce medical errors. She said the members should listen to experts in different areas, and determine what can be done to help reduce medical errors and then put that information together in a packet for distribution.

Dr. Aristeiguieta thanked everyone for their participation and comments, and adjourned the meeting at approximately 10:00am.