Is Physician Peer Review A Broken System?
Monday, March 9, 2009
2:00 – 4:30 p.m.
State Capitol, Room 4203
John L. Burton Hearing Room

ISSUE:

In 2000, the Institute of Medicine published *To Err is Human* which stated that about as many as 98,000 people die each year from medical errors in hospitals.[1] *To Err* points out that errors also occur in other medical settings such as outpatient surgical clinics and physicians' offices, and also in retail pharmacies, nursing homes and with other home care providers. Among the problems that commonly occur during the course of providing health care are adverse drug events, improper transfusions, surgical injuries and wrong-site surgery, suicides, restraint-related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities. High error rates with serious consequences are most likely to occur in intensive care units, operating rooms, and emergency departments. These errors are not only financially costly but could lead to the public's loss of trust in the system and diminished satisfaction by patients and other health care professionals. The report points out that a comprehensive approach to patient safety is needed, and given the indispensable nature of health care, high quality patient care is vital. Patients expect their treating physicians or other medical professionals to be competent and qualified, and physicians who fail to meet established professional standards must be discovered, reviewed and disciplined if necessary in a timely manner.

Physician peer review is one of the regimes used to ensure that quality of care is delivered while minimizing medical errors and managing patient risks. During a peer review, physicians evaluate their colleagues' work to determine compliance with the

[1] *See* generally Institute of Medicine, *To Err is Human*, Recommendation 6.1 (1999). The IOM made several recommendations on changes to the health care system. Specifically on peer review, Recommendation 6.1 states that Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

standard of care. Reviews are intended to detect incompetent or unprofessional physicians early and terminate, suspend, or limit their practice if necessary. Peer review is triggered by a wide variety of events including patient injury, disruptive conduct, substance abuse, or other medical staff complaints. A peer review committee investigates the allegation, comes to a decision regarding the physician's conduct, and takes appropriate remedial actions. However, there is reluctance among physicians to serve on peer review committees due to the risk of involvement in related future litigation, including medical malpractice lawsuits against a physician under review. In addition, there has been rising concern relating to "sham peer review." Sham peer review is the use of the peer review system to discredit, harass, discipline, or otherwise negatively affect a physician's ability to practice medicine or exercise professional judgment for a non-medical or patient safety related reason. Other criticisms of peer review include over legalization of the process, lack of transparency in the system, and burdensome human and financial toll peer review brings not only to the hospital but also to a physician under review. In addition, a legislatively mandated report calls the peer review system in California "broken and in need of a major fix if the process is to truly serve the people."[2]

The goal of this hearing is to give a brief overview of peer review in California and provide a clearer understanding on how hospitals and other entities conduct peer review. The hearing also includes discussion on a legislatively mandated report on peer review authored by Lumetra and what changes may be necessary to improve peer review and ensure that the basis for its existence, the protection of the public, is upheld.

BACKGROUND:

A. **Current Peer Review System in California**

Medical Board and 805 Peer Review Reporting Requirements

The Medical Board of California (MBC) is responsible for regulating and licensing physicians in California. The MBC revokes, suspends, or limits the practice of any physicians and surgeons. In exercising regulatory authority over physicians and surgeons the MBC has as its highest priority the protection of the public. Currently, the MBC regulates 125,612 physicians and surgeons, of which 97,878 reside in California. The MBC investigates complaints against physicians and adopts final decisions in disciplinary matters against physicians and surgeons.

In 1975, the California Legislature passed the Medical Injury Compensation Reform Act of 1975 (commonly referred to as MICRA) to limit the legal liability of health care providers and included special rules for medical malpractice cases. MICRA encompasses all of the following: 1) limits the contingency fee counsel may receive in medical

[2] *See Comprehensive Study of Peer Review in California: Final Report*, 1 (2008), available online at http://www.mbc.ca.gov/publications/peer_review.pdf.

malpractice cases; 2) vests the MBC with the responsibility to protect the public from incompetent physicians; 3) permits a health care provider charged with medical malpractice to introduce evidence of a patient's receipt of compensation from "collateral sources" such as insurance policies; 4) limits the time in which a medical malpractice action can be commenced; 5) requires a patient to provide 90 days' notice of his or her intent to sue to encourage settlement; 6) permits a contract for medical services to include a binding arbitration requirement; 7) permits periodic payment awards, rather than a lump sum award, for future damages; and 8) imposes a strict limit of $250,000 on non-economic damages.[3] Legislative analyses, when MICRA was adopted, indicates that the primary purpose of MICRA was to reduce the cost of medical malpractice litigation and restrain a perceived explosion in the cost of medical malpractice insurance while preserving the rights of medical malpractice victims to receive sufficient compensation for their injuries.

As part of MICRA, the California Legislature enacted the basic provisions of state law governing medical peer review and mandatory reporting to the MBC (see Business and Professions Code Sections 800-809; all further Code Section references will be to the Business and Professions Code unless otherwise noted). Section 805 requires any "peer review body"[4] to report certain information to the MBC or other relevant physician licensing agency when specified criteria are met. Generally, an "805 report" is required whenever a doctor's application for membership or staff privileges is denied for medical disciplinary reasons, or membership, staff privileges, or employment is terminated, revoked, or restricted for medical disciplinary reasons.[5] In addition, if a doctor resigns in the face of an investigation by a medical peer review body, a report is required. Although the primary reporting obligation lies with hospitals, health plans, physician groups, professional societies and clinics also have reporting obligations.

According to the MBC, it received one hundred thirty-eight 805 reports in 2007-2008 from hospitals/clinics (74), health care service plans (17), and medical group/employers (47). Out of all of these reports, one accusation was filed, 92 cases are pending disposition and 45 cases were closed. The number of 805 reports varies from year to year but it appears that when adjusted to the number of physicians and surgeons licensed and living in California, or the number of people living in California, the trend shows a downward direction.[6] Pursuant to Section 805, the information reported to the MBC is confidential in nature. Section 805 also specifies that <u>willful failure</u> to file an 805 report

[3] *See* Civil Code § 1431.2. Defines non-economic damages as non-quantifiable damages, including compensation for pain and suffering.

[4] Peer review body includes a medical or professional staff of any health care facility or clinic licensed by the Department of Public Health, or a facility certified to participate in the federal Medicare Program as an ambulatory surgical center; a health care service plan registered under the Knox-Keene Act or a disability insurer; any medical, psychological, marriage and family therapy, social work, dental, or podiatric professional society with membership of at least 25 percent of the eligible licentiates in the area in which it functions; or a committee organized by any entity consisting of or employing more than 25 licentiate of the same class that functions for the purpose of reviewing the quality of professional care provided by members or employees of that entity.

[5] *See* Business & Professions Code § 805 (b).

[6] *See* Lumetra study, *supra* note, at 12-15.

is punishable by a maximum fine of $100,000 per violation and any failure to file an 805 report is punishable by a fine of $50,000.

In 1989, several due process provisions for physicians subject to an 805 report were adopted and codified under Section 809 *et. seq*. of the Business and Professions Code. Committee analysis on SB 1211 (Keene, Chapter 336, Statutes of 1989), which contained the provisions of Section 809, indicated that the California Medical Association (CMA) was the sponsor of the legislation, and on the due process provisions of the measure, CMA indicated that "the clear procedural standards in SB 1211 will reduce the risk of erroneous peer review decisions." Under Section 809, any physician, for which an 805 report may be required to be filed, is entitled to specified due process rights, including notice of the proposed action, an opportunity for a hearing with full procedural rights (including discovery, examination of witnesses, formal record of the proceedings and written findings). Furthermore, a physician may seek a judicial review in the Superior Court pursuant to Code of Civil Procedure Section 1094.5 (writ of mandate). It should be noted that the due process requirements do not apply to peer review proceedings conducted in state or county hospitals, to the University of California hospitals or to other teaching hospitals as defined.[7]

Hospitals and other medical entities are charged with ensuring that physicians receive their 809 due process rights and these entities usually err on the side of caution to avoid potential liability for inadequate compliance with the 809 due process requirements. Some experts and stakeholders indicate this had resulted in a lengthy, costly and over-legalized system. In addition, there seems to be confusion as to when an 805 report must be filed with the MBC. Many hospitals are waiting to file an 805 report until due process provisions of 809 are exhausted but this delay may result in a physician continuing to practice below the standard of care, thereby increasing patient risks.[8]

Department of Public Heath and Hospital Peer Review Requirements

The California Department of Public Health's Licensing and Certification Program (DPH) licenses, regulates, and inspects hospitals and other health care facilities throughout California. SB 1312 (Alquist), Chapter 895, Statutes of 2006, gave DPH the authority to assess hospitals an administrative penalty of up to $25,000 for a violation or deficiency that constitutes an immediate jeopardy to the health and safety of a patient. An immediate jeopardy is defined as a situation in which a hospital's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

DPH regulations require all hospitals to have an organized medical staff and to also have formal peer review procedures in place as part of their licensing requirements. DPH has also issued more stringent peer review requirements for hospitals engaging in medical specializations such as heart surgery.[9] All DPH licensed healthcare facilities are required

[7] *See* Business & Professions Code § 809.7.
[8] *See* Lumetra study, *supra* note 2, p. 65.
[9] *See* § 70433(a)(2) of Title 22 requiring pre and post procedure case management review.

to have an organized medical staff which establishes controls to ensure that physicians practicing at the faculty meet all required ethical and professional standards.

Title 22 § 70703 of the California Code of Regulations requires a medical staff committee in all hospitals licensed by DPH. Section 70703 requires that each hospital have an organized medical staff made up of qualified physicians empowered to establish written by-laws detailing the formal procedures for, "the evaluation of staff applications and credentials, appointments, reappointments, assignment of clinical privileges, appeals mechanisms and such other subjects or conditions which the medical staff and governing body deem appropriate."[10] The medical staff is required to meet regularly and to keep written minutes of its meetings. Further, the medical staff shall provide rules and regulations for the practices and procedures to be used at the hospital. The medical staff is also to engage in continuing education and maintain evidence of participation. The hospital governing body and medical staff are given significant leeway in implementing peer review procedures.

Members of the medical staff must continuously demonstrate competence in their specialty. Title 22 § 70701(7) requires the medical staff "establish controls" that are designed to ensure the achievement and maintenance of high standards of professional practice including provision "that all members of the medical staff . . . demonstrate their ability to perform surgical and/or other procedures competently and to the satisfaction of an appropriate committee or committees of the staff . . . at the original application . . . and at least every two years thereafter."

B. **Federal Requirements and other Industry Standards**

Federal Requirements

Recognizing that peer review is necessary to maintain and improve quality medical care, Congress in 1986 enacted the Health Care Quality Improvement Act (HCQIA).[11] HCQIA established standards for hospital peer review committees, provided immunity for those who participate in peer review, and created the National Practitioner Data Bank (NPDB). The NPDB is a confidential repository of information related to the professional competence and conduct of physicians, dentists, and other health care practitioners. Credentialing bodies are required to check the NPDB database before granting privileges to physicians or re-appointing them. Entities such as hospitals, professional societies, state boards, and plaintiffs' attorneys are given access to the NPDB. In enacting the NPDB, the United States Congress intended to improve the quality of health care by encouraging State licensing boards, hospitals, and other health care entities, and professional societies to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State without disclosure or discovery of previous medical malpractice payment and adverse action history.

[10] *See* California Code of Regulations Title 22 § 70703(b).
[11] *See* 42 U.S.C. § 11101 *et seq*.

The NPDB is a central repository of information about: (1) malpractice payments made for the benefit of physicians, dentists, and other health care practitioners; (2) licensure actions taken by State medical boards and State boards of dentistry against physicians and dentists; (3) professional review actions primarily taken against physicians and dentists by hospitals and other health care entities, including health maintenance organizations, group practices, and professional societies; (4) actions taken by the Drug Enforcement Administration (DEA), and (5) Medicare/Medicaid Exclusions.

It appears that hospitals may not be complying with the reporting requirements of the NPDB. In a 1995 report, the Office of Inspector General of the Department of Health and Human Services found that for the period September 1, 1990, when the NPDB became operational, to December 1993, about 75 percent of all hospitals in the country did not report an adverse action. More current data indicates that for the period September 1990 through September 30, 1998 about 67% of hospitals have never reported an adverse action.[12]

The most recent numbers suggest many of the trends highlighted above continue. The 2006 National Practitioner Data Bank Annual Report[13] highlights many of the same issues reported above continue to be a problem; including a diminishing number of reports. The 15,843 Medical Malpractice Payment Reports received during 2006 are 8.3 percent less than the number of Malpractice Payment Reports received by the NPDB during 2005. This decrease comes after a decrease of 2.2 percent in 2005 in comparison to 2004.[14] Of those hospitals currently in "active" registered status with the NPDB, 48.9 percent have never submitted a Clinical Privileges Action Report. This percentage has slowly decreased over the years, from 53.4 percent in 2004 and 52.0 percent in 2005.[15]

Industry Standards

Private standard setting is also common in peer review. Organizations like the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations or JCAHO), which accredits over 4,000 hospitals, health care providers and other health care settings across the country have established peer review standards for the entities it accredits. In order to receive Joint Commission accreditation, hospitals must have peer review and other quality assurance measures. Eligibility for federal funds such as Medicare and Medicaid often depends on accreditation. In 2004, the Joint Commission renamed peer review into "*Focused Review of Practitioner Performance*" which was later renamed to *Focused Professional Practice Evaluation* (FPPE). In 2007, the Joint Commission defined two types of reviews aimed at assuring physician

[12] *See* Office of Inspector General, United States Department of Health and Human Services, *Legislative Recommendation to Improve Hospital Reporting to the National Practitioner Data Bank* (May 28, 1999) *available at* http://oig.hhs.gov/oei/reports/oei-12-99-00250.pdf.
[13] *See* U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, Division of Practitioner Data Banks *2006 National Practitioner Data Bank Annual Report* (2006) *available at* http://www.npdbhipdb.hrsa.gov/pubs/stats/2006_NPDB_Annual_Report.pdf.
[14] *Id.* at 6.
[15] *Id*. at 8.

competence: the FPPE and "ongoing professional practice evaluation" (OPPE.) The FPPE applies to new applicants for medical staff membership and to existing practitioners requesting new privileges for which the hospital has no documented evidence of their competence. FPPE may also apply to a practitioner whose current abilities are questioned because of negative performance issues or because an adequate volume of cases are not available to assess current competence. In the case of initial medical staff appointments, the hospital must check with primary sources to determine whether the practitioner requesting medical staff membership and privileges has the requisite current training, knowledge, skills and abilities. These same parameters must be evaluated for practitioners during the re-credentialing process, with the additional requirement that granting of privileges is based in part on the results of peer review and OPPE. Proctoring is a form of focused evaluation involving one-on-one evaluation of a practitioner's performance by another peer practitioner (a proctor). Direct observation is used to gauge the ability of the proctoree to perform a procedure or use a new technology. Focused proctoree evaluation may occur retrospectively through peer review if on-site, real-time evaluations are not feasible. In the case where same specialty peer reviewers are not available internally, external peer review can be used as a viable substitute for on-site proctoring.

In 2007, the Joint Commission established OPPE because of the recognition that there is need to evaluate practitioners on an ongoing basis rather than at the usual two year reappointment process and allow practitioners to take steps to improve performance on a more timely basis. OPPE applies to practitioners who have already been granted patient care privileges, to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal. The revised OPPE process requires a clearly defined process for the evaluation of each practitioner's professional practice which would include the following: who will be responsible for reviewing performance data, how often the data will be received, the process to be implemented to make a decision on whether to continue, limit or revoke privileges, and how the data will be incorporated into the credentials' files? OPPE standards require an evaluation for all practitioners and not just those with performance issues.

Federation of State Medical Boards Standards

The Federation of State Medical Boards (FSMB) is a national organization of seventy state medical boards established to continuously improve the quality, safety and integrity of health care through developing and promoting high standards for physician licensure and practice. In 1998, the House of Delegates of the FSMB established the Special Committee on the Evaluation of Quality of Care and Maintenance of Competence (Committee) to assist state medical boards in assuring standards of quality and competence within their jurisdictions.[16] The Committee stated that as protectors of the public health and safety, state medical boards are ultimately accountable for the quality of health care provided by physicians within their jurisdictions as well as for assuring

[16] *See* Federation of State Medical Boards of the United States, *Report of the Special Committee on Evaluation of Quality of Care and Maintenance of Competence*, May 1998, *available at* http://www.fsmb.org/pdf/1999_grpol_Evaluation_of_Quality_Care.pdf.

physician licensees are competent to practice medicine. Among other things, the Committee was charged with evaluating and analyzing current procedures utilized by state medical boards in identifying and investigating complaints involving the quality of care rendered by a physician; recommending to state medical boards methods to liaison with peer review groups, third party players, peer review organizations, to enhance the boards' ability to evaluate complaints regarding quality of care as well as determining ongoing competence of physicians; recommending enhanced methods of obtaining information and utilizing personnel in the evaluation of complaints regarding quality of care; and recommending the most effective/appropriate methods of investigating complaints regarding quality of care. The Committee came up with twelve recommendations, specifically on the identification, evaluation and investigation, disposition, assessment and remediation of quality of care issues and strategies to enhance quality of care and assure maintenance of physician competence.[17] Lumetra highlights the Federation standards in order to illustrate the general consensus among state medical boards regarding their proper role and overall responsibility in assuring quality of care and competence of practitioners. Lumetra underscores the importance that peer review plays in identifying physicians who fail to provide quality of care and in the MBC taking appropriate action as necessary to improve the physicians practice in problematic areas.

C. The Lumetra Report – Comprehensive Study of Peer Review in California

SB 231, Figueroa, Chapter 674, Statutes of 2005, required the MBC to contract with an independent entity to conduct a comprehensive study of the existing peer review process. SB 231 required specific components of the study, including: a comprehensive description of the various steps of and decision makers in the peer review process; a survey of peer review cases to determine the incidence of peer review; assessment of the cost of peer review to licentiates and the facilities which employ them and the average time consumed on peer review proceedings and an assessment of the need to amend Section 805 and Section 809 of the Business and Professions Code to ensure that they continue to be relevant to the actual conduct of peer review. Lumetra was chosen by the MBC to conduct the study and the report was submitted to the Legislature on July 31, 2008.[18] In the report, Lumetra concluded that "the present peer review system is broken for various reasons and is in need of a major fix, if the process is to truly serve the citizens of California."[19]

The study surveyed California's peer review bodies, including hospitals, healthcare plans, professional societies, and medical groups/clinics. The survey included entities from the entire state of California and represented both urban and rural entities as well as public and private entities. The chart below identifies study participation:

Entity type	Population	Final Sample	% of

[17] *See supra* note 2, at 67-87 for a discussion on how the Medical Board of California has applied the FSMB quality of care standards.
[18] *See* Business & Professions Code § 805.2.
[19] *See* Lumetra study, *supra* note 2.

			Population
Hospitals	366	132	36.1%
Health care plans	51	28	54.9%
Professional Societies	9	9	100%
Medical groups/clinics	123	76	61.8%
Total	**549**	**245**	**46.5%**

Medical entities, particularly hospitals, exhibited a substantial amount of anxiety about providing Lumetra with the information they requested. Over one third of hospitals communicated with Lumetra via their attorneys. A number of entities or their attorneys sent letters to Lumetra detailing their reasons for refusing to submit the requested information to Lumetra. Most of these letters reference a telephone conference call held on October 5, 2007 which was arranged by the California Hospital Association. This conference call was ostensibly to allow Lumetra to address concerns and answer questions that the hospitals had regarding the information Lumetra sought. According to Lumetra, "a few individuals dominated the call and expressed a desire to substantially change the study design."[20] Due to the conference call and other concerns Lumetra set up a website that described the study purposes, pertinent legislation, and posted answers to frequently asked questions.

Lumetra outlined the vital information categories which it sought information from medical entities regarding their peer review process including peer review hearing minutes, peer review and hospital by-laws, and other related documents. Unfortunately, despite a legislative mandate and immunity from discovery or other adverse action for disclosure of the information to Lumetra, it encountered significant problems gathering the information from the medical entities it surveyed. Many entities refused to comply with the requests for a variety of reasons; the two most common reasons given by entities for non-participation were: (1) lack of time/resources/staff to provide the information; and (2) fear of legal discovery/breach of confidentiality requirements.

Lumetra describes these informational requests as "Requirements." Requirement one sought from entities a "comprehensive description of the various steps and decision makers in the peer review process as it is conducted by peer review committees . . . including policies, procedures, bylaws, charters, and peer review minutes from 2002-2007."[21] 70.2% of entities did not submit the information requested under Requirement one with 82.6% of hospitals declining to submit all the requested information. Requirement two requested a "survey of peer review cases to determine the incidence of peer review by peer review bodies and whether they are complying with the reporting requirement in Section 805."[22] Lumetra reports a "substantial amount of anxiety about the study exhibited by entities, particularly hospitals" with many entities communicating through attorneys and declining to submit important documents such as committee minutes.[23] Reporting was higher with only 43.7% of entities refusing to fully respond.[24]

[20] *See* Lumetra study, *supra* note 2, at 63.
[21] *See* Lumetra study, *supra* note 2, at 51.
[22] *See* Lumetra study, *supra* note 2, at 63.
[23] *Id.*

The unwillingness of medical entities to disclose their by-laws, minutes, and other related documents to Lumetra made it difficult for Lumetra to judge the effectiveness and appropriateness of the entity peer review process and entity compliance with the stated process.

Findings of Lumetra's Study:

1) **Variation and inconsistency in entity peer review policies and standards**. Variations exist on the definition, procedures, commencement, practice and subject of peer review. Peer review means different activities to different entities, and can be triggered by a number of ways but is mostly part of the quality/safety/risk process of an entity. In addition, risk management/peer review issues are combined with mundane issues related to the "business" of an entity. All medical entities set their own standards for peer review, some more rigorous than others, and some adhere to them more meticulously than others. Additionally, each entity creates its own peer review policies, which can vary substantially. If a physician is found to provided substandard care, that physician may leave or be forced to leave the entity but can practice elsewhere, potentially endangering other patients.[25] The peer review process is often lengthy and can take months or even years. There are also variations on the name of the peer review body, the number of members and the length of time a member serves on a committee (usually could be years before a peer review action is taken).

2) **Poor tracking of peer review events**. Many entities, especially hospitals, expressed anxiety and concern in providing documents for review, particularly peer review minutes, due to fear of legal discovery. Most entities do not have their documents in electronic form and do not have readily accessible tracking systems that would allow staff members to efficiently follow events over time.

3) **Confusion on 805 reporting**. Few cases lead to actual 805 reporting because (1) of disagreement or legal interpretation on whether 809 due process is required before every 805 report is submitted, and, (2) 809 due process leads to a substantial delay in the process (often 2 to 5 years). In addition, although entities make a sincere effort to conduct peer review, it rarely leads to actual 805 or 809 actions, perhaps due to the confusion over when to file a report. In addition, entities have devised other methods to correct a physician behavior before filing an 805 report. The most common cases being referred to a high level peer review are: disruptive physician behavior/impairment, substandard technical skills, substance abuse, and failure to document/record patient treatment. It is also possible that some physicians would never be subject to peer review because they have practices that are not subject to any peer review requirements.

4) **Lack of coordination among state agencies, and licensing agencies**. There is no systematic communication or coordination among various boards and

[24] *See* Lumetra study, *supra* note 2, at 51.
[25] *See* Lumetra study, *supra* note 2, at 105.

agencies that would coordinate patient quality and safety issues. There is much complexity on the complaint process, enforcement process, and the public disclosure rules that apply to the MBC. There is also criticism that the MBC may not quickly investigate all 805 reports, or if reports were investigated, the MBC often did not find any wrongdoing. In addition, others indicated that MBC's follow-up for 805 reports took as long as one year after submission of a report. It is unclear what factors provide barriers to a more effective and efficient process. It is also not clear that MBC receives valid and complete information from entities or individuals when investigating 805 reports, even with subpoena power.

5) **Burdensome costs of peer review.** Latest data indicates that an estimated 0-250 hours was spent on peer review activities. Most of the respondents (68%) indicated that the cost estimate in the last calendar year was between $0-50,000 excluding physician costs in time. Cost to an individual physician ranged from $0-$50,000; focus group participants indicate that an 809 hearing would never cost less than $100,000, excluding estimates of physician costs in time and legal representation for the person being reviewed, and could cost upwards of several million dollars.

Lumetra Study Recommendations:

1) **Redesign the peer review process and create an independent review organization.** Allow the current peer review system to continue where a health care entity acts as a "first level" screener, as defined, and continues to investigate complaints and conduct periodic reviews of physicians. If a physician's action related to patient care does not meet the standards of care at the screening, then the physician would be referred to an unbiased independent review organization with no vested interest in the review outcome. The independent review organization then conducts its own investigation, including random site visits and audits, and makes recommendations regarding the filing on an 805 report or any other action. A copy of all recommendations would be sent to the MBC. Any serious issues/events would be "fast-tracked" and reported to the independent review organization within five hours. The independent review organization would then investigate and take immediate action. The independent review organization would also be responsible for maintaining a database and a tracking system to monitor trends.

2) **Improve transparency of the entire peer review process**. The MBC would notify interested parties when an investigation begins, concluded, and when changes will be made on the MBC's website regarding a physician's status. The MBC website must be redesigned to include more information available indefinitely to the general public about a physician's profile, and the website must be redesigned to make it user-friendly to the general public so that the average layperson can chart and understand the entire process with minimal difficulty.

3) **Revise role of the MBC.** The MBC would continue to investigate all 805 reports, and make determinations about any licensee's action. MBC would be required to initiate an investigation within 48 hours of receiving an 805 report, and make recommendations within 5 days of completing the investigation.

4) **Revise due process hearings or 809 process**. Remove 809 hearing process from health care entities and have the independent review organization or the MBC conduct them to ensure fairness and timeliness. Create a professional jury of practicing physicians comprised of all licensed physicians who rotate and serve for a set period of time. Eliminate the requirement that the MBC obtain a subpoena for documents related to a complaint or broaden subpoena power to include all related medical and peer review hearing related documents.

5) **Emphasize credentialing and re-credentialing**. Credentialing and re-credentialing should still occur at the healthcare entity level and the healthcare entity would report any changes in credentialing or privilege to practice to the independent review organization.

6) **Promote education of physicians, entities, and the general public**. The MBC should create programs to continuously educate and update all physicians and employees of health care entities required to submit 805 reports and any related laws and regulations. Further, patient and public rights must be clearly summarized on the MBC's website. Lastly, the MBC is to emphasize to entities that there are penalties for failure to file an 805 report.

7) **Clarify and improve specific provisions of existing law.** The Legislature should clarify whether or not an 809 hearing is required prior to submission of an 805 report; or whether or not the hearing before the 805 is only waived after a summary suspension of greater than 14 days or a termination/revocation of privileges. Further, there is a need to clarify whether or not failure to complete patient records should trigger an 805 report. The MBC and Legislature should require a tracking system in each entity and require peer review body minutes to be maintained and available for a period of 5 years which is separate from all other committee business. Require all medical facilities and groups to have peer review bodies and procedures as well as being made subject to 805 reporting requirements. Define specifically what peer review consists of and what events trigger a peer review.

8) **Identify Funding Source**s. Funding is needed to implement these recommendations and funding sources could include increasing licensing fees, charging malpractice insurance companies a percentage of the premiums they receive, charging entity attorneys a percentage of their billing incomes, and use a percentage of malpractice awards to fund the process.

9) **Pilot Project**. The Study specifies that these recommendations be made part of a 5-year pilot program to determine which have positive and negative impacts on

peer review reporting and whether or not further fixes or changes are needed.

Responses to Lumetra's Report:

Medical Board of California

The MBC states that it agrees with Lumetra's conclusion that the current peer review system has several flaws and concerns. The MBC supports reforms that involve other state agencies who have regulatory authority over reporting entities. The MBC points out that 805 reports are critically important because its own statistics reveal that approximately 30% of 805 reports it received result in disciplinary actions. The MBC uses the 805 reports as a road map to investigate a physician whose clinical skills, conduct, or competence is called into question. Generally, the MBC obtains a subpoena to gather necessary information and medical records from a reporting entity to further its own investigation. Once the appropriate records are obtained, the matter is reviewed to determine if there is any violation of the Medical Practice Act.

Below is a summary of MBC's response to Lumetra's report:

1. **Enhancements to the peer review system**. The MBC states that although it has no authority to direct the manner in which peer review is performed in settings licensed by other regulatory agencies, such as the Department of Public Health or the Department of Managed Health Care, it supports any enhancements to standardize, improve, and expedite the peer review system.

2. **Greater transparency**. The MBC agrees with Lumetra's report that there is a need for greater transparency on the public disclosure of physician information on the Medical Board's website. The MBC indicates that it will implement a process in which a summary of actions and reasons for the actions will be added to a physician's profile on the website upon completion of an investigation.

3. **Subpoena requirement**. The MBC concurs with Lumetra's report that there is a need to eliminate the requirement that a subpoena must be obtained to acquire information from reporting entities. If the subpoena requirement is eliminated, the time it takes for the MBC to investigate a physician's action would decrease and further enhance public protection.

4. **Education**. The MBC supports additional education requirements for physicians on the regulatory requirements of peer review, ideally on the medical school level. In addition, reporting entities need to be educated as to when and how to report so there is no confusion with the 805 reporting requirements.

5. **Clarify the codes**. The MBC states that although it believes that the law is quite clear when an 805 report must be filed, the findings of Lumetra's report indicate there is a need to clarify the reporting requirements. The MBC also points out that it is currently seeking legislation to repeal Business and Professions Code

Section 821.5, which requires an entity to report to the MBC's Diversion Program a physician whose ability to practice medicine is impaired by a disabling mental or physical condition, because the Diversion Program has been eliminated. According to the MBC, the requirements contained in Section 821.5 fall under existing Section 805 categories for reporting.

California Medical Association (CMA)

The California Medical Association has published a response to Lumetra's report in which it makes a variety of criticisms and comments. CMA identifies what it considers to be issues with the methodology, conclusions, and recommendations contained in Lumetra's report.

CMA's criticisms of the methodology center on Lumetra's inability to gather enough information about the individual peer review regimes used by various medical entities. CMA claims that the surveys used by Lumetra were poorly designed and the hospitals did not respond or completely respond to the surveys. CMA also suggests that since the Joint Commission promulgated new standards, the peer review environment has changed significantly. CMA states that these changes were not considered by Lumetra. CMA also argues that the number of 805 reports should not be considered an indicator of quality peer review.

CMA also commented on the conclusions made in Lumetra's report. CMA disputes many of Lumetra's conclusions citing its criticisms of the methodology used in the study. Specifically, CMA believes that without more information it is impossible to conclude that there is inconsistency across entities and that there is a lack of consistent tracking of peer review events within entities. CMA agrees that there might be an issue with objectivity, neutrality, and confidentiality of peer review. CMA also points repeatedly to the new Joint Commission 2007 standards and how they were not considered when writing the report. CMA also agrees with Lumetra's report that there might be entities avoiding the "spirit" of 805, that all entities do not conduct peer review, excessive delays create barriers to public protection, and that the costs are prohibitive.

Lastly, CMA responded to Lumetra's recommendations on how to improve the peer review process. CMA disagrees with Lumetra's recommendation that a new independent peer review entity might be needed. CMA states that independent peer review might be appropriate in some instances, to be decided on a case-by-case basis. CMA states it is in favor of transparency, but not before a final decision is reached as it is concerned about the impact prematurely released information can have on a doctor's career. CMA opposes Lumetra's recommendation that 805 reporting and 809 due process responsibilities be removed from the medical entity level and transferred to an independent entity. CMA believes that in certain circumstances that independent entity 805/809 peer review responsibility might be appropriate, but only on a case-by-case basis. Lastly, CMA believes that certain recommendations such as emphasizing credentialing, promoting education on the 805 requirements, and clarification of the legal codes might have merit and should be studied further.

California Hospital Association (CHA) – Peer Review Work Group

The Peer Review Work Group ("Work Group") was formed to consider reforms and "best practices" for peer review with the goal of increasing efficacy, fairness, and usefulness of the peer review process. The Work Group is made up of representatives of the CHA, CMA, and other interested parties including hospitals, medical staffs, chief medical officers, hearing officers, and former chiefs of staff. The Work Group published a response memorandum to Lumetra's report ("Memorandum"), which was submitted to the Senate Business, Professions, and Economic Development Committee on March 3, 2009. The Memorandum has three subsections: (1) comments on Lumetra's findings; (2) comments on Lumetra's recommendations; and, (3) alternative recommendations. Many of the Work Group's comments echo CMA's responses discussed above.

Part 1 contains responses to Lumetra's findings and includes thirteen subparts. The Work Group expressed many concerns with the findings made by Lumetra including: the finding that peer review has failed, that inconsistency of peer review standards is a problem, that the length of time needed to complete an 805 report is too long, that the lack of consistent tracking across medical entities is a problem, that there is a lack of unbiased, objective, and confidential review at medical entities, that lack of transparency is actually a problem, that entities are avoiding following the "spirit" of § 805, and that the reporting requirement causes confusion among anyone but the most senior level hospital executives. The Work Group's criticism and comments focused on the assumption that since Lumetra was unable to gather critical information the report is flawed. Part 1 indicates that it is critical that individual entities determine what works best in their facilities and that physicians' rights can only properly be protected by in-entity peer review.

Part 2 contains the Work Group's comments on Lumetra's recommendations. The Work Group states that, "[w]e fear . . . that if Lumetra's recommendations are adopted, the "cure" would be worse than the "disease." The Work Group made seven comments on Lumetra's recommendations. The Work Group opposes the establishment of an independent peer review body claiming it will add complexity and cost to the system and independent peer review is not true peer review. The Work Group also states that Lumetra's recommendation of "improving transparency" goes against the stated goal of the peer review regime as implemented by the Legislature and interpreted by the courts. It argues that confidentiality is necessary to protect physician rights. Furthermore, the Work Group opposes further education on 805 reporting and clarifying the provisions of § 805 because it argues that only certain members of a medical entity actually need to understand the reporting requirements and these members already understand them. Further they argue if there is confusion regarding the law, attorneys can be consulted to clarify the requirements.

In Part 3 the Work Group makes alternative recommendations for improving peer review. They argue that the negative impact and costs of 805 reporting outweigh the benefits in

many instances. The Work Group argues that the 805 process affects physicians' careers, unnecessarily burdens medical staffs and hospitals, and costs too much money and time. They advocate modifying the 805 reporting requirements by increasing the threshold at which 805 reports are required to be filed and to focus more on remedial and educational solutions to a greater range of quality of care issues. Although the Memorandum does not specify to what point the threshold should be raised one can assume that they consider the current system's threshold to be too low. They suggest that there are many issues requiring attention for the medical staff which should not require an 805 report.

D. Case Study: Failure at Redding Medical Center

One particularly disturbing illustration of the failure of the peer review process took place at Redding Medical Center (RMC). RMC is one of two hospitals in Redding, California, with 238 beds, and was owned by Tenet Healthcare Corporation (Tenet). RMC operated an open-heart surgery program called the California Heart Institute which draws patients from many areas of Northern California. In 2003, Tenet agreed to pay $54 million to resolve government accusations that doctors at RMC conducted unnecessary health procedures and operations on more than 600 patients between 1995 and 2002. According to several newspaper articles and a Congressional report entitled *How Peer Review Failed at Redding Medical Center, Why It is Failing Across the Country and What Can Be Done About It*, two directors of RMC (Dr. Chae Hyun Moon and Dr. Fidel Realyvasquez) were performing 4 – 5 times as many cardiac procedures and surgeries than would have been expected for the hospital and the population it served. Although staff physicians complained to RMC administrators beginning in 1996, no corrective action was taken until there was a Federal Bureau of Investigation raid in 2002, prompted by a complaint by a priest.

Although hospital administrators and state regulators received numerous reports of potential quality of care issues at RMC, no substantial corrective action was taken. *The Redding Report* authors conclude that the two directors of the program along with hospital administration, and staff blocked peer review; successfully hiding the negligent medical practice for ten years. In fact, one of the directors, Dr. Moon, had been subject to hospital suspension every single day of 1992. Rather than being restricted, Dr. Moon was one of the busiest physicians at the Center during that time.

While the Redding Medical Center case is a particularly egregious example of the current problem of the physician peer review process, it illustrates how the process can be manipulated and sub-standard physician performance can be overlooked, hidden, or ignored for an extended period of time. *The Redding Report* points out that there is a long history of similar cases in which effective peer review could have made a difference.

E. Conclusion

The current peer review process was adopted with the specific goal of replacing medical malpractice claims (limited by MICRA) as the means of ensuring quality care with a statewide regulatory regime. Ideally, the medical entities promptly investigate and report

805 issues to the MBC. The MBC then investigates and comes to a licensing decision in a timely manner. Unfortunately, at least in some high profile cases, this has not been the reality. Medical peer review has become an impediment to effectively protecting patients.

Peer review is perhaps the most important tool in reducing medical errors and increasing patient safety measures. However, the process has increasingly been fraught with issues, from the reluctance of physicians to serve as peer reviewers, the high financial costs associated with peer review, the control granted to medical entities to develop their internal procedures, and to the abuse of the process through the use of sham peer review, many stakeholders are debating on how to improve the process to serve its well intended purpose. The findings and recommendations contained in Lumetra's study serve as a starting point to continue the discussions on streamlining and improving the peer review process to create a system that benefits health care entities, physicians, and the public at large. Obviously, Lumetra was prevented from receiving important information and data it needed to make more concrete conclusions regarding the peer review process and what in particular may be broken about the system.

More information is needed on the peer review system in order to accurately diagnose when it succeeds in protecting patients and when it fails to identify and appropriately deal with unprofessional behavior. If it is determined that the system is beyond repair (that is the MBC and the health care entities are unable to identify and deal with issues which affect patient health in a timely manner) then there may be a need to examine and consider new methods of ensuring patient safety.