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Comprehensive Study of Peer Review in California: Final Report

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Table of Contents

List of Figures

List of Tables

List of Appendices

- General Office Practices/Protocols: Frequently Asked Questions
- Medical Malpractice Reporting: Frequently Asked Questions
- Physician Credentials/Practice Specialties: Frequently Asked Questions
- Public Information/Disclosure: Frequently Asked Questions
- Complaint Process - Frequently Asked Questions
- Brochure: “How Complaints are Handled”
- Consumer Complaint Form
- Authorization for Release of Medical Information
- Brochure: Information Services for Consumers
- Confidential State Agency Consumer Response Form
- Reporting Requirements for Coroners
- Manual of Model Disciplinary Orders and Disciplinary Guidelines, 9th edition, 2003
- Health Facility/Peer Review Reporting Form
- Peer Review Body Initial Report Form to the Physician Diversion Program Regarding an Investigation of a Mentally or Physically Disabled Physician
- Peer Review Body Final Report Form to the Physician Diversion Program Regarding an Investigation of a Mentally or Physically Disabled Physician
- Report of Settlement, Judgment, or Arbitration Award
- Physician Reporting - Criminal Actions
- Reporting Requirements for Court Clerks
- Health Facility/Peer Review Reporting Form
- The Hot Sheet: A Summary of Administrative Actions: editions from January 2007 to May 2008
- Brochure: “Questions and Answers about Investigations”
- Brochure: “Most Asked Questions about Medical Consultants”
- Notification of Name Change
- Request for Copy of 805 Report
- Outpatient Survey - Patient Death Reporting Form
- Patient Transfer Reporting Form

Appendix VIII: Other States

- Massachusetts Board of Registration in Medicine Patient Care Assessment (PCA) Division: Instructions for Completing Safety and Quality Review Form
- Chart outlining each state’s existing statute or legislation and PSO, reporting requirements, and pending legislation
- Federation of State Medical Boards: 2008 Legislative Services Update

Appendix IX: Comments About Study

- Comments from Web Page
- Comments about Survey
- Comments about Study Process
- Survey Participant Comments by Question
- Participant Comments via Letters**the last document I sent goes with these

- Participant Survey Short Answer Responses by Question

Appendix X: California Health Plans, Clinics, and Hospitals

- Map of California's Rural Hospitals
- List of Critical Access Hospitals in California, April 13, 2007
- Critical Access Hospital Program: Designation Protocol
- Chart Outlining OSHPD, name of organization, county, contact information, and clinic type
- Chart Outlining OSHPD, name of organization, county, contact information, clinic type, number of beds, and EMS level
- List of Small and Rural Hospitals Open as of January 1, 2008
- Department of Managed Health Care List of All Licensed Plans, May 9, 2008

Executive Summary

In October 2005, Governor Arnold Schwarzenegger signed into law California Senate Bill 231 (Figueroa), which, among other things, amended the California Business and Professions Code 800, including Section 805.2.

Section 805.2 provided for a comprehensive study of the physician peer review process, as conducted by peer review bodies. Another equally important component of this study was to evaluate the continuing validity of Section 805 and Sections 809 to 809.8, inclusively, and their relevance to the conduct of peer review in California, since they play such a critical role in ensuring quality medical care.

Lumetra, a non-profit healthcare consulting organization with 24 years of experience in California, was selected as the independent entity to conduct this peer review study, which was to be completed by July 31, 2008. The study, designed around the requirements of the 805.2 legislation, focused on four entities involved in peer review activities: 1) Licensed healthcare facilities/clinics, 2) Healthcare service plans, 3) Professional societies, and 4) Medical groups. The research was quantitative and qualitative, cross-sectional, retrospective, and descriptive. Multiple data collection methods were employed, including document review, surveys, focus groups, key informant interviews, and onsite visits.

The study generated controversy and anxiety among the four entities, particularly hospitals. Their concerns ranged from the time and expense to provide documents for review to reluctance in releasing legally protected information for "fear" of discovery. Lumetra was able to respond to and overcome these barriers and produce statistically valid findings from the data that were collected from study participants.

This report presents these findings, which enabled us to draw several conclusions about the state of peer review in California and make sound recommendations to improve the current system.

Findings

The complete findings are presented in Chapter IV: Results. One finding that was apparent is 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. This report cites the inconsistencies in the way entities conduct peer review, select and apply criteria (e.g., implicit vs. explicit review), and interpret the law regarding 805 reporting and 809 hearings.

These variations can result in physicians continuing to provide substandard care (at times for years) impacting the protection of the public. We also found that, 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. And there is evidence that entities do not understand what should trigger a peer review, 805, or 821.5 reporting. Additionally, the costs in time and money associated with 805 reporting are high and may influence an entity's desire to actively pursue a case against a physician and choose a less expensive alternative (e.g., resignation, remediation, etc.).

This study also examined the role of the Medical Board of California (MBC) and assessed its effectiveness in the regulation of the practice of medicine in California. We found the MBC procedures for the complaint and enforcement process and the rules for public disclosure to be complex and multi-layered. The MBC is sometimes viewed as only intermittently responding to 805

reports (particularly focusing on those events that result in patient harm), unacceptably delaying the response, and failing to report public information. While the MBC obviously has earnest intentions about protecting the public's health, its bureaucracy and current mode of operation may create barriers. And in all fairness to the MBC, it is somewhat hampered by current laws and legislation.

Recommendations

The study findings led to recommendations that are logical, practical and, most importantly, achievable. They also address the relevant study requirements specified in the 805.2 legislation. The complete list of recommendations appears in Chapter V.

One major recommendation is to re-design the peer review process, including establishing a separate, independent peer review organization that has no vested interest in the review outcome, except the protection of the public. Each of the four entities would still provide the first level quality/safety screening of the physician practice, but the independent agency would assume the responsibility for making decisions about any actions toward the physician, including 805 or 821.5 reporting. The establishment of an unbiased third party would eliminate the inconsistencies, variations, and conflicts of interest that confront and baffle entities that perform peer review. The MBC would continue to investigate all 805 reports and make determinations about any license actions.

Less dramatic but equally important recommendations involve correcting the transparency issue (e.g., through improved public disclosure), emphasizing credentialing and re-credentialing as a means to identify and further investigate potential physician practice problems, and promoting education to better inform physician and entities about peer review and 805 and 809 reporting criteria. We recommend that the codes be clarified, especially as they relate to the timing of when to report an 805. We also offer suggestions on ways to fund these recommendations that would not involve increasing taxes or diverting State funds.

Finally, we emphasize the importance of pilot studies and program evaluation in implementing any system change and recommend that any change be phased in over time to allow adjustments by the affected systems and entities.

Lumetra appreciates the opportunity to have a major role in trying to measure, evaluate, and improve peer review in California.

Chapter I: Introduction

In October 2005, Governor Arnold Schwarzenegger signed into law California Senate Bill 231 (Figueroa), which, among other statutory changes, amended the California Business & Professions Code 800, including Section 805.2.

Briefly, it is the intent of 805.2 "to provide for a comprehensive study of the peer review process, as it is conducted by peer review bodies," by an independent firm selected by the Medical Board of California (MBC). A primary goal of the study is to "evaluate the continuing validity of Section 805 and Sections 809 and 809.8, inclusive, and their relevance to the conduct of peer review in California." The due date for the written report of this study was extended to July 31, 2008 (from the original due date of July 31, 2007).

This Report details the findings of the Peer Review Study for the Medical Board of California and the California State Legislature. It encompasses the 10 required components of the Study, as dictated by Section 805.2.

Table 1.1 lists the ten required components for the Comprehensive Study of Peer Review (Peer Review Study) and the mechanisms used by Lumetra to satisfy each component.

Table 1.1: Comprehensive Study of Peer Review Report Components

Comprehensive Study of Peer Review Components[1]	Mechanism Used by Lumetra
1) A comprehensive description of the various steps of and decision makers in the peer review process as it is conducted by peer review bodies throughout the State, including the role of other related committees of acute care health facilities and clinics involved in the peer review process.	Entity documents, surveys, site visits
(2) 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.	Entity documents and site visits
(3) A description and evaluation of the roles and performance of various State agencies, including the State Department of Health Services and occupational licensing agencies that regulate healing arts professionals, in receiving, reviewing, investigating, and disclosing peer review actions, and in sanctioning peer review bodies for failure to comply with Section 805.	MBC site visit and data analysis
(4) An assessment of the cost of peer review to licentiates and the facilities which employ them.	Survey and focus groups
(5) An assessment of the time consumed by the average peer review proceeding, including the hearing provided pursuant to Section 809.2, and a description of any difficulties encountered by either licentiates or facilities in assembling peer review bodies or panels to participate in peer review decision-making.	Survey and focus groups
(6) An assessment of the need to amend Section 805 and Sections 809 to 809.8, inclusive, to ensure that they continue to be relevant to the actual conduct of peer review as described in paragraph (1), and to evaluate whether the current reporting requirement is yielding timely and accurate information to aid	Survey, focus groups, and key informant interviews

Comprehensive Study of Peer Review Components[1]	Mechanism Used by Lumetra
licensing boards in their responsibility to regulate and discipline healing arts practitioners when necessary, and to assure that peer review bodies function in the best interest of patient care.	
(7) Recommendations of additional mechanisms to stimulate the appropriate reporting of peer review actions under Section 805.	Survey, focus groups, and key informant interview
(8) Recommendations regarding the Section 809 hearing process to improve its overall effectiveness and efficiency.	Survey, focus groups, and key informant interview
(9) An assessment of the role of medical professionals, using professionals who are experts and are actively practicing medicine in this State, to review and investigate for the protection of consumers, allegations of substandard practice or professional misconduct.	Surveys, key informant interviews, and MBC visit and data analysis
(10) An assessment of the process to identify and retain a medical professional with sufficient expertise to review allegations of substandard practice or professional misconduct by a physician and surgeon, if the peer review process is discontinued.	Surveys, key informant interviews, and MBC visit and data analysis

Following a competitive review process, the MBC selected Lumetra as the independent firm to conduct the Peer Review Study.

As an independent healthcare consulting firm with nearly 24 years of experience in healthcare program evaluation and peer review analysis in California, Lumetra understands well the nuances and political landscape of California's variety of healthcare entities, including hospitals, clinics, health plans, medical groups, and professional entities and societies - the key targets of this study.

Section 2220.1 provided for the appointment of an independent enforcement monitor, charged with evaluating "the disciplinary system and procedures of the board, making as his or her highest priority the reform and reengineering of the board's enforcement program and operations and the improvement of the overall efficiency of the board's disciplinary system."

In November 2005, the MBC and the legislature received the final report from the Enforcement Monitor[2, 3]. Two of the findings, listed below, are related to the work of this study, because they describe limitations of the MBC.

> "…5**. Many of MBC's most important detection mechanisms are failing it.** Despite the extensive "mandatory reporting scheme" set forth in Business and Professions Code section 800 et seq., the Medical Board is not receiving information to which it is statutorily entitled (underlining added for emphasis) about civil judgments, settlements, and arbitration awards against physicians, criminal convictions against physicians, or hospital disciplinary (peer review) actions against physicians as required by law - information that enables MBC to detect possible physician wrongdoing, investigate, and take disciplinary action as appropriate.
>
> Further, physicians themselves routinely conceal information about their own misconduct from the Board through the insertion of **"**regulatory gag clauses**"** (underlining added for emphasis) — provisions that prohibit an injured plaintiff from complaining to or cooperating with the Medical Board — into civil malpractice settlement agreements….

6. **The Medical Board's public disclosure policy is insufficient.** The Board's complex public disclosure statutes and regulations — which have evolved in patchwork-quilt style over the past decade — do not allow the Board to disclose sufficient information about physician conduct and history (underlining added for emphasis) to enable patients to make informed decisions about their physicians (p. ES-5)…"[3].

The Legislature took steps to address the recommendations in the final Fellmeth and Papageorge report, including closing the gag clause loophole[3]. However, it is not clear that the MBC is even now receiving information "to which it is statutorily entitled," nor is it clear that the MBC is able to "disclose sufficient information about physician conduct and history" to protect the public.

In preparing this report, we note the following exclusion and limitation to this study. The Peer Review Study excludes Allied Health Licensing Programs (AHLP). The MBC serves not only physicians and surgeons, but also several "allied health licensing programs" that regulate non-physician healthcare practitioners.

In recent years, most AHLPs have successfully sought legislation creating discipline-specific boards. However, some of them still contract for the use of components of MBC's enforcement program to varying degrees. Because the intent of SB 231 (Figueroa) was to assess the physician and surgeon peer review programs, we have generally excluded peer review of AHLP. Additionally, the AHLP reviews constitute only a small proportion of overall MBC workload.

A limitation of this report was the reluctance of many of the entities, particularly hospitals, to provide access to documents (specifically peer review committee minutes) needed to estimate the efficacy and efficiency of peer review.

Although the legislation (and subsequently the law) states that any documents provided to the independent entity are not "discoverable," several entity staff members reported that hospital attorneys had advised clients to not provide peer review committee minutes because of California Evidence Code 1157. Therefore, verification of hospital compliance with policies and bylaws was difficult.

In some cases, the entities **only** communicated with Lumetra through attorneys. In spite of these obstacles, Lumetra reviewed documents from 68 entities (excluding site visits) from the four entity types and was able to estimate the overall efficacy of medical peer review process in the State.

This report is organized as follows:

- Chapter I is an introduction.
- Chapter II provides the background and significance of the study.
- Chapter III discusses the study methodology and details each study component and mechanism used to collect data for each component.
- Chapter IV presents the study results.
- Chapter V provides conclusions and recommendations based on the findings.

Chapter II: Background and Significance

Introduction

In order to understand the complexity and challenge of Sections 805, 821, and 809, and their requirements, Chapter II provides a background of the MBC, an overview of medical peer review, a historical perspective which has significantly influenced the peer review process, and the relevant codes and regulations that govern the practice of medicine in California today.

Medical Board of California

The Medical Board of California (MBC) is a State government agency, which licenses and disciplines medical doctors. In 2007, the MBC regulated 124,056 physicians, 96,299 of whom resided in California. The MBC receives no funding or support from the State's general fund, rather it is funded entirely by physician licensing, renewal, and application fees; as such, it is characterized as a "special-fund agency." The California Business and Professions Code, Section 2001.1, defines the highest priority of the Medical Board as:

> "Protection of the public shall be the highest priority for the Medical Board of California in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount"[4].

The Board provides two principal types of services to consumers: 1) public-record information about California-licensed physicians and 2) investigation of complaints against physicians[4].

The Board does not regulate health plans or insurance companies. The Department of Managed Healthcare (http://www.dmhc.ca.gov/default.aspx), in the Business, Transportation and Housing Agency, regulates California health plans, and the Department of Insurance (http://www.insurance.ca.gov/) regulates insurance companies in the Executive Branch of State government[5].

Although physicians are closely associated with hospitals and clinics, those facilities are regulated by other agencies. The California Department of Public Health (CDPH) (http://www.cdph.ca.gov/Pages/default.aspx), within the California Health and Human Services Agency (CHHS) (http://www.chhs.ca.gov/Pages/default.aspx), regulates hospitals and clinics. However, the California Department of Healthcare Services (DHCS) (http://www.dhcs.ca.gov/Pages/default.aspx) contracts for Medi-Cal and other services and, therefore, has some regulatory relationship with primary and rural health (which includes come clinics and hospitals), and long term care.

The MBC is semi-autonomous in that its members make final licensing and enforcement decisions (subject to judicial review). MBC was composed of two autonomous divisions - the Division of Licensing (DOL) and the Division of Medical Quality (DMQ). These two divisions were abolished, effective January 1, 2008, by AB 253.

Now, the Board as a whole manages the business that was formerly managed by the two divisions. The Board focuses on the licensure of physicians and the regulation of several non-physician healthcare professions, oversees a large enforcement staff, and adopts final decisions in disciplinary matters against licensees[3, 6].

Overview of Medical Peer Review

In academia, scholars use peer review as a way to subject their work to criticism by discipline-specific experts. It serves to help normalize high standards and expectations and prevents unwarranted conclusions or interpretation in research. The notion of medical peer review is similar, that is to review and critique the work of a colleague in order to maintain high standards of medical care. It has been defined as:

> "a process where selected members of the medical or other professional staff review the basic qualifications (credentials), medical outcomes and professional conduct of other physicians or licensed professional members and staff applicants, to determine whether the professional may practice or continue to practice in the hospital or other clinical setting and, if so, to determine the parameters of their practice" (p. 1)[7].

There is a long history of the relationship between hospitals and physicians related to patient quality and safety. Prior to 1846, hospitals were essentially almshouses for the poor that gradually became a place to care for the sick. With the advent of anesthesia in 1846 by Morton, the emphasis on sanitation by Nightingale in the Crimea in 1854, and Lister's work in antiseptics in 1867, hospitals began to become safer for surgical patients[8]. During the late 19th century, the hospital medical staff members could generally be categorized as:

1. Consulting physicians who had no regular duties
2. Resident or house physicians who supervised treatment
3. Residents or house physicians in training who carried out treatments
4. Dispensary physicians who saw outpatients

Hospitals paid none of these doctors for their work. The physicians provided their services without pay in order to train, have access to surgical suites, gain prestige, and add patients to their private practices. A small elite group of physicians held hospital appointments (privileges), and physicians outside that elite group resented the "unjust" control exerted by a "ring of monopolists" (p. 166)[8].

Generally, the American College of Surgeons is credited with beginning medical peer review in 1918[9] or 1919[8] as part of its Hospital Standardization Program. The medical staff members of hospitals were required to be "competent reputable physicians abide by formal bylaws, and hold monthly meetings and reviews of clinical experiences" (p. 107)[8].

However, Glaser wrote in 1963, "…Granting or withdrawing hospitalization privileges [in other countries] cannot be used to regulate professional and personal behavior; in fact, this use of hospitalization privileges makes America one of the few countries with any controls over the quality of private practice" (p. 54)[10].

In contrast, Starr opined that it was never clear that withdrawing hospital privileges was effective at raising quality of private practice, but there was no doubt that it was used to exclude undesirables[8]. He maintained that it was used to exclude black doctors and "anyone else who threatened to rock the boat" (p. 168)[8]. So, from the beginning of modern medical care in the US, physicians, surgeons, and hospitals were mutually dependent, physicians were generally not paid for their work in the hospital, and granting or withholding hospital privileges was used to try to ensure quality care, but was also thought to be used for "political" reasons, such as excluding "undesirables."

It is not surprising that the question of whether peer review and restriction of hospital privileges are used to exclude "undesirables" remains. The phrases "sham peer review" or "peer review injustice" refer to the use of the peer review process to eliminate "mavericks, whistleblowers, rivals, and nonconformists" (p. 1)[11].

These issues are often raised by physicians who have had negative experiences with peer review. Others in the medical-legal community claim that this is just "sour grapes" from people who deserved disciplinary action. However, there are such a growing number of concerns raised about peer review injustice, that it has become more difficult to ignore the complaints.

The Association of American Physicians and Surgeons has a Web page listing numerous opinion pieces, presentations, news reports, and court causes related to sham peer review[12]. A physician from that organization opines that the sham process "begins in the minds of those who set out to destroy a targeted physician" (p. 3)[13].

Others use stronger language to describe sham peer review in medicine calling it "workplace mobbing" and allege that it is used to rid an entity of a troublemaker or to rid an "insider" physician of a competitor[14]. This is reiterated in a publication describing the peer review process as "misused, ineffective, and corrupt"[11].

The literature mentions two general types of peer review: implicit and explicit. Implicit peer review relies on expert judgment and is typically performed by a physician. Explicit peer review, frequently used by nurses, involves applying a specific set of criteria[15].

Evidence of reliability of the methods is mixed. A report comparing the two methods found many discrepancies in findings. In the discordant cases, physicians tended to find quality problems unavoidable, there was no adverse outcome, or they were present on admission[16]. Another report found unstructured implicit review was not a reliable method for determining error and measuring compliance with standards[17]. However structured implicit review tended to be moderately reliable and certainly more reliable than unstructured implicit review[15, 18, 19].

Peer review in the U.S. is closely related to the credentialing and re-credentialing of providers, the method used to restrict or allow hospital privileges, and it continues to be linked with disciplinary action in the form of allowing or withdrawal of hospital privileges[7]. Although there was a movement by hospitals in the 1980s and 1990s to focus on systems analyses rather than individual blame to control error, the difficulty of changing systems provided a barrier to this notion. Therefore, individual blame continues to be a large part of error management in hospitals.

In medical-care-providing entities, quality, risk, or error management customarily begins in one of several ways:

1. A complaint
2. As the result of a routine quality screening study
3. A sentinel or egregious event
4. An unexpected adverse outcome or other triggers

The issue/case then goes before one or more peer review bodies. There may be one of several results of the peer review investigation within the entity that affects the physician:

1. Nothing
2. Mandatory education or training
3. Monitoring or proctoring procedures and practices
4. Mandatory behavior counseling or some variant
5. Change/restriction in privileges
6. Summary suspension or termination.

Some of these results require reporting to state or national agencies and may have an impact on the physician's livelihood and ability to work. But whether the result is positive or negative for the physician, the peer review process is a significant part of the investigation and any discipline that occurs. Because of the link between peer review and disciplinary action, physician generally are apprehensive about the process of peer review, whether as a recipient or as a reviewer.

If the event that triggered the peer review investigation meets the criteria for reporting to a state medical board, disciplinary action by the medical board may occur. A number of studies have reported characteristics of physicians who have been disciplined by medical boards, including being male[20-23], not being board certified[20-22, 24], not being white[21], being a foreign medical graduate[21, 22], and increasing age[22, 25].

Specialties that tend to be disciplined more frequently include anesthesia, psychiatry, internal medicine/family practice, obstetrics and gynecology, and emergency medicine[21-24, 26]. Interestingly, lower patient-provider communication scores were associated with higher numbers of retained complaints made to regulatory authorities[27].

The complaints were both communication-related complaints and quality-of-care complaints. Also, lower scores on traditional written examinations that tested clinical decision-making at the end of medical school were also associated with higher numbers of communication and quality of care complaints[27]. Among other findings, these studies provide support for the notion that foreign medical graduates and non-whites are disciplined more frequently than U.S.-trained graduates and whites.

One of the most difficult issues facing entities is working with a physician who is incompetent, disabled, disruptive, or impaired[28, 29]. Leape has suggested categorizing "problem doctors" as psychopathic, impaired, demonstrating declining competency, or demonstrating behavioral problems[28]. These categories are not mutually exclusive, and one type of issue frequently is related to another.

The most common reasons for disciplinary actions taken by medical boards against physicians are impairment related to drugs or alcohol, negligence or incompetence, and drug-related charges/inappropriate prescribing practices[20, 24]. The issue of incompetence, dyscompetence[30], or underperformance are often addressed first by recommending or requiring continuing medical education (CME) or skill training and monitoring or proctoring[31, 32]. However, it has not been demonstrated that CME or skill training is effective in changing practice behavior of physicians[25]. There is evidence that some physicians who are incompetent have some type of cognitive impairment that accounts for the poor performance. This cognitive or neuropsychological impairment has been found more frequently in the elderly physician[33, 34].

An even more difficult issue facing entities is managing the physician with cognitive difficulty, alcohol or drug impairment, or disruptive behavior. The latter is typically defined as the use of profane or

disrespectful language, demeaning behavior, throwing instruments, and anger outbursts, among others[28]. Entities typically ignore these behavior problems for extended periods of time and may not manage them at all[28].

Some state medical boards have developed diversion programs that seek to monitor physicians with drug or alcohol problems rather than discipline them. The programs became popular in the 1980s with California creating the first such program in 1980[35]. Initially, evidence indicated that this program was successful in encouraging the treatment of physicians[36]. However, the California Medical Board recently voted to terminate the program effective 2008 after multiple audits determined that the program did not protect patients[37].

Malpractice litigation increased between 1840 and 1850[38]. If a medical error led to patient injury, the patient had the option of suing the physician for malpractice. Previous to that time period, medical doctors had advertised flamboyant successes and made exaggerated claims of cures. Additionally, there were few regulatory statutes or professional standards of medical practice and education[38]. The public became unwilling to tolerate unfavorable medical outcomes. Other issues were involved, but also during this time, the relationship between doctors and lawyers deteriorated and remains tenuous today.

Malpractice litigation also encouraged and continues to encourage holding individual providers accountable for poor outcomes and perpetuates the blaming of an individual rather than considering systematic problems as the cause. Risks of malpractice litigation include being a surgeon and having a higher number of patient complaints and increased patient volume[39]. Interestingly, the majority of technical errors in surgery were associated with experienced surgeons. These errors occurred in routine operations and involved patient-related complexity[40].

Errors and the threat of malpractice take a toll on physicians as well as on patients. There is evidence that some specialty physicians reduce the number of high-risk procedures they perform in order to control their risk of malpractice litigation. Some neurosurgeons in Florida are reported to have reduced the volume of brain surgeries they perform, and patients have had to travel longer distances to obtain care[41].

Physicians report increased anxiety, sleep loss, job dissatisfaction, and harm to their reputation following serious errors[42, 43, 44]. In 1975, California legislators passed the Medical Injury Compensation Reform Act of 1975 (MICRA)[45], codified in the California Civil Code Section 3333.2. Medicine and hospital trade entities hailed this legislation as the action that kept doctors' offices opened and increased patient access to healthcare. Others note that malpractice litigation has declined in California since the legislation was passed and that the $250,000 limit on "pain and suffering" has not been altered since 1975.

Disclosure of errors to patients and reporting of errors are topics that often leave physicians conflicted. Generally, physicians want to be transparent but are fearful of litigation, embarrassed, or unsure of the best way to disclose[42, 46, 47]. Some reports provide evidence that disclosure of errors to patients is associated with a reduced likelihood in the patient changing physicians, increased patient satisfaction, trust, and a positive emotional response. However, there was mixed evidence about whether the patient was likely to seek legal advice[48, 49]. Another report found that disclosure was not associated with reduced litigation volume or cost[50].

Today, hospitals typically do not "employ" most physicians, although there are exceptions (i.e., contracted anesthesiologists, ED physicians, and hospitalists). Rather, the relationship of mutual

benefit between physician and hospital persists as it has in the past. There is no "employer-physician" relationship, and physicians perform work at the hospital, such as participating in peer review, usually without compensation in exchange for the privilege of admitting patients. Additionally, there are few recognized employee-employer safeguards in the hospital-physician relationship, other than those provided in the medical staff bylaws or those that can be won in litigation[51].

Because the physician needs a place for acutely ill patients and the hospital needs patients, the relationship is generally smooth. However, when there are potential quality issues, there are several liability "landmines": 1) anti-trust issues; 2) due process issues; and 3) ethical dilemma issues[51]. Although legal protection exists, there is the potential that a reviewed physician, whose privileges have been terminated, might litigate alleging that the peer review (or reviewer) was used to eliminate competition[52]. This type of litigation generally fails, as long as the decision was made in good faith[51].

Another potential litigation issue is the allegation of the denial of the protection of due process. Because of a number of successful lawsuits related to due process, such as Potvin v. Metropolitan Life Insurance Company[53], hospitals feel compelled to err on the side of caution and increase the number of protections for the physician[51]. In that case the California Supreme Court held that a managed care entity cannot terminate one of its panel physicians unless it accords that physician a fair hearing with basic due process protections[53].

Another issue of concern is that of the ethical dilemma. When reporting an error or reporting a colleague, the individual will weigh the consequences of the actions that might be taken:

- Potential improvement of patient care quality and safety and knowledge that you are doing the right thing, versus,
- Potential for anti-trust or due process violation litigation and potentially creating a rift among the medical staff group that may lead to tension, a loss of referrals, and/or a decrease in peer cooperation (such as emergency coverage for your patients)[51].

As discussed previously in regard to disclosure, physicians are generally moral individuals who try to do the right thing, but the negative consequences of reporting are significant and will undoubtedly be weighed by thoughtful, intelligent people.

805 Reporting – A Historical Perspective

In 2001, the California legislature added Section 805.2 to the Business and Professions Code requiring the MBC to contract with the Institute of Medical Quality, a subsidiary of the California Medical Association, to engage in a comprehensive study of the way in which peer review was actually conducted in California at that time, and to compare the process with the reporting language in section 805. The study report was to be completed by November 1, 2002, which was later extended to November 1, 2003[54].

When the study was not performed due to budget shortfalls, SB231 (2005) amended 805.2 to require MBC to contract with an independent entity to conduct the 2001-mandated study by July 31, 2007. The 2007 deadline was later extended to July 31, 2008[3].

The specific language and requirements of the study of peer review is documented in Table 1.1. The peer review process, as defined in the legislation, is essential to maintaining safe, quality medical care for California citizens. However, the peer review process is obscure[55], and it is not clear that the MBC receives reports as required by law.

Based on absolute numbers, 805 reporting has varied over time and, based on number of reports adjusted for population of citizens or population of physicians, the number has declined (see Figures 2.1, 2.2, 2.3, and 2.4). This decline is not an isolated event to California. The January 1995 Newsletter of the California Medical Board stated, "Over the past year, we have noted deterioration in the cooperation required between hospitals and the Board in protecting consumer/patient safety. We have experienced incomplete reports, and on some occasions, excuses for not reporting at all[56].

The Federation of State Medical Boards reported a decline in reports of disciplinary actions against physicians by medical boards in the U.S. beginning in 2005 and continuing through 2006 and 2007[57, 58]. Baldwin et al reported a low and declining level of hospital privileges action reporting to the National Practitioner Data Bank between 1991 and 1995[59]. The Office of the Inspector General reported that as of September 30, 1998, only about 67 percent of U.S. hospitals had made a report[60], and issued another report in 2001 warning that the database was underused[61].

Historical events in the State and nation likely influenced the number of 805 reports submitted to the MBC (see Figure 2.1). In the mid-1990s, managed care penetration increased substantially in California with the objective of controlling costs[62, 63]. Hospitals instituted dramatic staffing reductions.

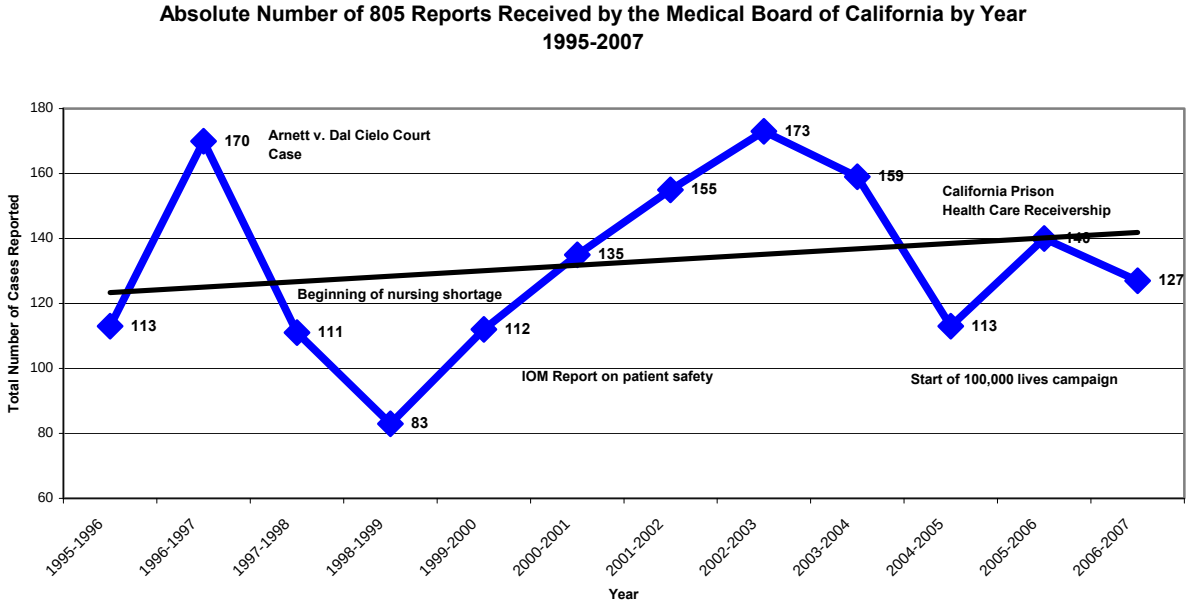
In 1996, the California Supreme Court clarified that a subpoena of peer review records by the Medical Board did not constitute "discovery" in the legal sense[64] and the Board had the right to enforce its subpoena for such records. This may have affected responses to 805 reporting and likely made entities more cautious and more reluctant to provide any information, other than what was specifically subpoenaed.

In 1997, the federal government passed the Balanced Budget Act[65], which put more financial pressure on hospitals and health plans to curb costs. The latest and very substantial nursing shortage started in hospitals in California in 1998[66, 67], and in 1999 California passed the first mandated hospital nurse to patient ratios legislation in the United States[68, 69]. This added more financial pressure on hospitals.

In 2000, the Institute of Medicine published To Err is Human[43], which generated publicity and interest in medical errors, particularly in hospitals. Even though the wording is "medical errors," it should be remembered that physicians are not responsible for all "medical" errors in hospitals. Many medical errors are related to the complex and chaotic systems in U.S. hospitals. (Note: This report will address complaints, errors, and events directly related to physician medical practice, not to system errors in the study entities.)

Figure 2.1 graphs the absolute number of 805 reports and includes major historical events that occurred over the 12-year period between 1995 and 2007. The added trend line indicates that the number of 805 reports increased during those years.

Figure 2.1: Absolute Number of 805 Reports Received by the Medical Board of California by Year, 1995-2007



However, if you adjust the number of 805 reports received by the MBC for the number of MDs licensed by the State (see Figure 2.2), the number of MDs licensed and living in California (see Figure 2.3), or the number people living in California (see Figure 2.4), the trend lines show a downward direction.

Figure 2.2: Number of 805 Reports per 1000 MDs Living Both In and Out of California by Year, 1995-2007

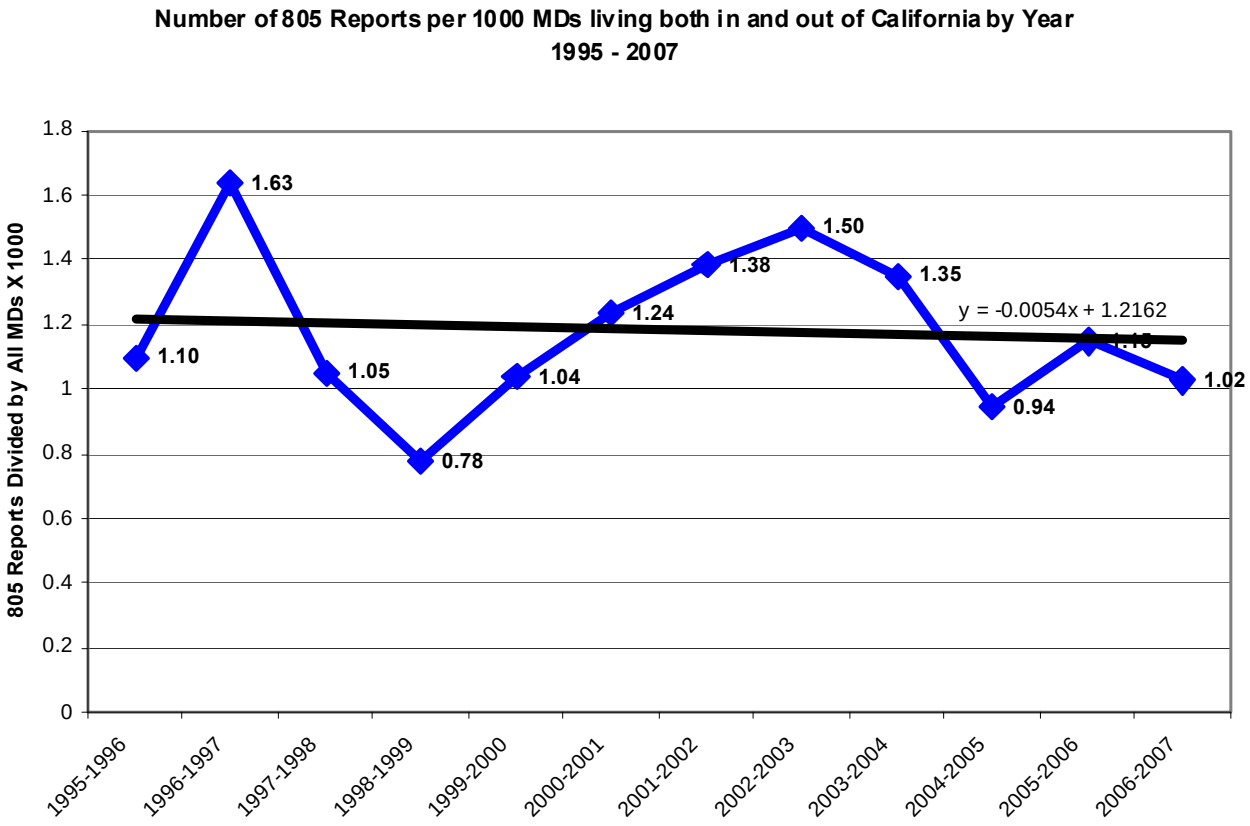


Figure 2.3: Number of 805 Reports per 1000 MDs Living in California by Year, 1995-2007

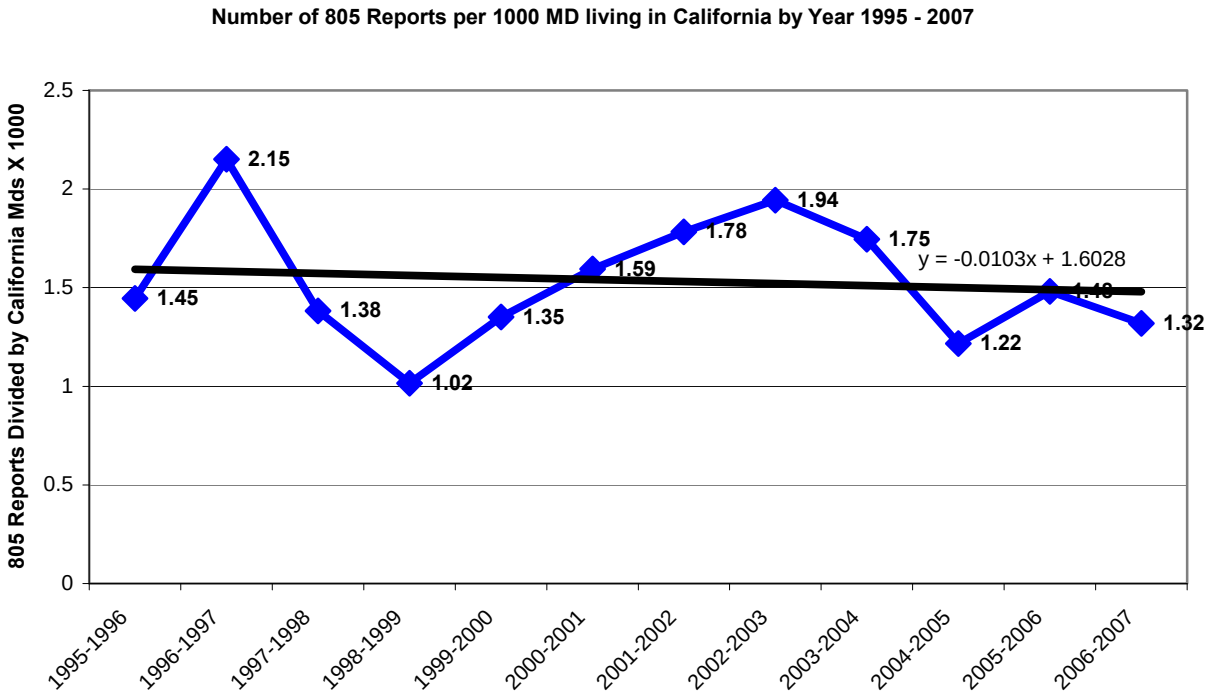
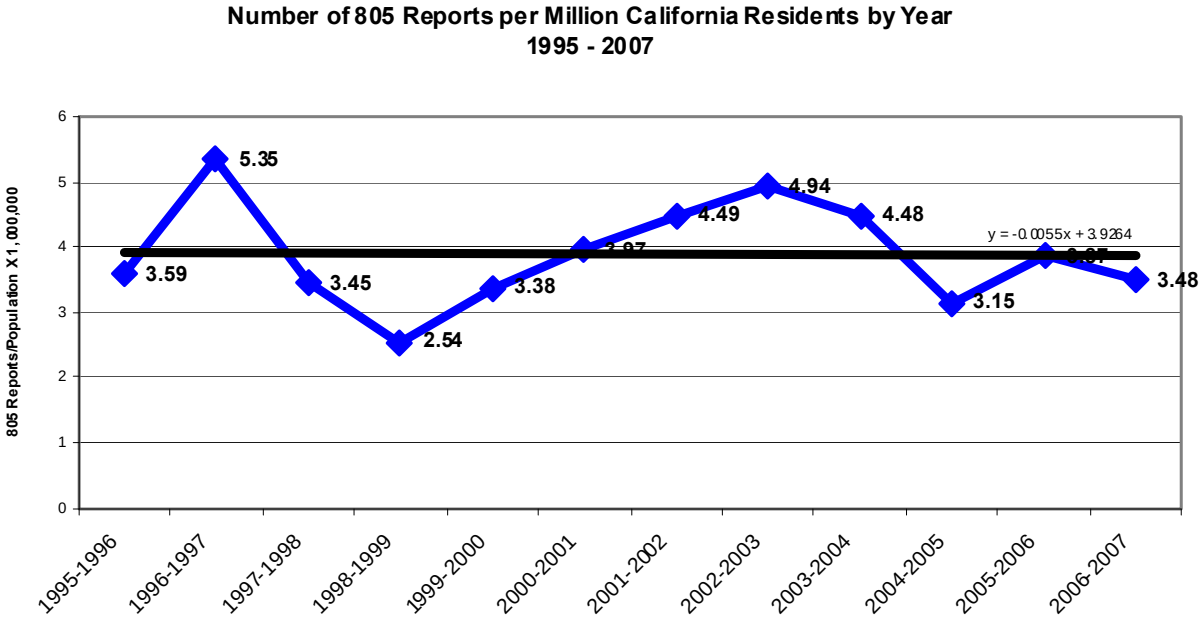


Figure 2.4: Number of 805 Reports per Million California Residents by Year, 1995-2007



These historical events likely influenced the California legislators to become interested in evaluating the mechanisms, such as peer review, used to assess medical care in the State. In this matter, the California Legislature was prescient. In 2005, the Federation of State Medical Boards announced

that reports of disciplinary actions against physicians by U.S. state and territory medical boards had declined in 2005 for the first time in eight years and declined again by 4.6% between 2006 and 2007[57, 58]. The time for this evaluation of peer review is entirely appropriate.

The Challenge and Future of Peer Review

In the years since 1918, the provision of medical care has evolved into a multi-national industry that includes numerous ancillary providers, mid-level providers, administrators, insurers, federal and state laws, attorneys, and others. Some of the questions raised during the early 19th century are still being raised today:

1. Should physicians be paid for work such as peer review in the hospital?
2. Are peer review and discipline using the withdrawal of hospital privileges effective in ensuring quality care?
3. Are peer review and exclusion from hospital privileges done for "political" reasons?

Some entities and states have proposed or tried new ways to determine quality and safety in medical care. Since 1987, the Massachusetts Medical Board has required all hospitals, physicians, and clinics to report adverse events through the Patient Care Assessment (PCA) program. All unexpected deaths and major complications must be reported quarterly through this confidential program, which is protected from legal discovery. A somewhat unique advantage of the Massachusetts Medical Board is that it has extensive authority over physician practice and healthcare facilities in the areas of quality, safety, and error prevention[70].

The Texas State Board of Medical Examiners uses an investigations process that includes the informal show compliance (ISC). The ISC is a mechanism that allows the physician to show that he or she has not violated the medical practice act. The physician can provide written documents and/or make a personal appearance and is encouraged to engage the assistance of an attorney. This process is not recorded and the rules of evidence do not apply, but it allows the board to provide recommendations to the physician and attempt to reach an agreement informally[71].

Other entities have suggested using independent review entities and adjusting for patient risk[72], providing confidential ongoing feedback[73], establishing or designating independent federal oversight through Patient Safety Organizations (PSO) in the U.S. Department of Health and Human Services[74], and using centralized supervision or regulation, practice guidelines, information technologies, and continuous quality improvement activities[75].

The literature seems to indicate that professionals are questioning whether peer review should continue to be the primary way that medical quality and safety are estimated. Some have even questioned whether there is still any place for medical peer review in determining quality and safety of medical care[11, 15]. There is evidence that with structured implicit review, physician-reviewers are less likely to record poor quality in surgical patients presenting with an acute illness[19], and discussion between physician reviewers does not improve the reliability of peer review hospital quality[76]. Other evidence indicates that developing an enhanced peer assessment using trained peer assessors in one-on-one interactions is a promising method of changing physician behavior[77]. Other suggested strategies include using:

1. Performance assessment rather than peer review[78].
2. Multi-source feedback to assess physician competencies[79].

3. Specialty certification status to measure quality[80].
4. Administrative data for some types of complications[81].
5. Standardized patients (actors trained to present certain symptoms to train and evaluate practitioners) to evaluate decision making[82].
6. Clinical vignettes to measure quality of physician practice[83].

However, California codes require the use of peer review in healthcare entities as one of the processes for determining safe and effective medical care, and they are used in defining who is required to report medical events to the licensing board (see Table 2.6).

Codes and Regulations

The codes that govern the practice of medicine in California are extensive and complex, but it is necessary to have a basic comprehension of these statutes in order to understand the process of medical peer review and event reporting and the challenges they present in conducting this study. In order to explicate the complexity of the laws, we provide a partial list of codes and regulations in the following tables.

Many of the laws (codes) related to medical practice in California are contained in various sections of the **Business and Professions Code** (B&P) (see Table 2.1)[84, 85].

Table 2.1: Select California Business and Professions Code

Topic	Section
General Provisions	Section 500
Physician Advertising	Section 651
Medical Malpractice Reporting	Section 801
Medical Practice Act Internet Information on Doctors License Required and Exemptions	Section 2000 Section 2027 Section 2050
Medical Assistants	Section 2069
Physician and Surgeon Licensing Information Requirements for Licensure Foreign Medical Graduates	Section 2080 Section 2080 Section 2100
Continuing Medical Education Outpatient Surgery Settings Enforcement Unprofessional Conduct Prescribing/Dispensing Reinstatement of License/Modification of Probation Diversion Evaluation Committee Medical Corporations Renewal of Licenses	Section 2190 Section 2215 Section 2220 Section 2234 Section 2241 Section 2307 Section 2340 Section 2400 Section 2420
Alternative Practices and Treatments	Section 2500
Licensed Midwives	Section 2505
Research Psychoanalysts	Section 2529

There are other State regulations, codes, sections of codes, and case law that dictate the highly complex business and practice of the science and art of medicine (see Table 2.2 and Table 2.3). We reference these laws in this report because they are relevant to the study. For example, letters from study respondents (see Appendix III: Hospital Related Documents) highlight the fact that entity attorneys made numerous references to Evidence Code 1157 and the Lanterman-Petris-Short Act as reasons for not providing peer review minutes for the study.

Two more examples of relevant law to this study are the Dal Cielo case, which was described by participants as a turning point in the relationship between the MBC and hospitals, and the Patrick case which relates to the issue of peer review and the issue of antitrust liability. The other laws listed are related to the issue of quality of care.

Table 2.2: Other California Laws and Cases Relevant to Peer Review

Regulations, Codes, Case Law	Relevance to Medical Practice
Arnett v. Dal Cielo; CA Supreme Court 1996[64]	The Court ruled that an investigative subpoena issued by the Medical Board of California as part of its inquiry into the conduct of a physician with an apparent drug problem is not "discovery" within the meaning of Evidence Code 1157
CA B&P Code 2027[86], 805.5 and 803.1[1]	Definition of what is publicly disclosed by the MBC
CA B&P Code 2056[86]	Protects against retaliation for physicians who advocate for medically appropriate healthcare for their patients
CA B&P Code 2222.07[87]	Elimination of the "Gag Clause" in malpractice suits
CA Code of Regulations Title 22[88]	Governs many aspects of hospitals and hospital care
CA Code of Regulations Title 28, Division 1, Chapter 1 (Sections 1300.41-1300.826)[89]	Detailed regulations under which healthcare plans must operate
CA Evidence Code Section 1157[55]	Provides that the records of a hospital peer review committee are not subject to discovery
CA Health & Safety Code Section 1278.5 (aka Whistleblower Protection for Healthcare Workers)	Protects patients, nurses, members of the medical staff, and other healthcare workers if they report suspected unsafe patient care and conditions
CA Health & Safety Code Section 1340-1345 (aka. Knox-Keene Healthcare Service Plan Act of 1975)[45]	The set of laws that regulate health maintenance entities (HMOs) in CA
CA Welfare & Institutions Code Section 5000 (aka Lanterman-Petris-Short Act of 1972)[90]	To guarantee and protect public safety; to safeguard individual rights through judicial review, specifically mentally disordered persons and persons impaired by chronic alcoholism
Patrick v Burget and the Healthcare Quality Improvement Act of 1986; U.S. Supreme Court, 1988[91]	The Court ruled that the state action doctrine (Parker v Brown)[92] does not protect Oregon physicians from federal antitrust liability for their activities on hospital peer review committees

*partial list

There are other laws governing the medical profession and entities that provide medical and health care, which try to ensure quality and safety of patients. Multiple persons and entities are required to report events to the MBC using different mechanisms. Additionally, consumers can file complaints directly to the Medical Board.

Table 2.3: Select California Codes Defining Who Must Report and What Gets Reported Related to Medical Practice*

B&P Code Sections	Who Reports and What is Reportable
801.1[1]	Physician self-reporting of settlements, judgments, or arbitration awards
802.1[1]	Physician self-reporting of indictment for felony or conviction of misdemeanor or felony
802.5[1]	Coroner report evidence of negligence or incompetence related to death
803[1]	Court clerks reporting of physician criminal actions
805[1]	**Peer Review body reporting of issues related to changes in entity privileges for medical cause or reason**
805 (j)[1]	No person shall incur any civil or criminal liability as the result of making any report required by this section
809.2[1]	Physician is entitled to fair hearing
820-828[93]	Peer Review Body reporting of physical or mental illness or substance abuse
2021[86]	Physician self-reporting of change of address within 30 days after each change
2220-2319[87]	MBC Enforcement; Definitions of reasons for discipline and unprofessional conduct; gross negligence and incompetence
2240[87]	Physician self-reporting of deaths while performing procedures outside hospital; ED transfers

*partial list

Two closely related federal laws also are related to medical event reporting and the goals of patient care quality and safety:

1. The Sherman Anti-Trust Act[52, 94]

2. Healthcare Quality Improvement Act (HCQIA) of 1986[95]
    a. National Practitioner Data Bank (NPDB)
    b. Healthcare Integrity and Protection Data Bank (HIPDB)

The Sherman Anti-Trust Act is important because physician practices are typically for-profit business entities and are subject to laws relevant to tax-paying entities, specifically laws about anti-competitive practices. Confusion can occur because hospitals and some health plans are nonprofit entities (non tax-paying). Thus the anti-trust act becomes particularly important when physician competitors are required to participate in peer review of each other.

The HCQIA created two databanks: 1) the National Practitioner Data Bank (NPDB) to which certain entities are required to report events related to medical practice; and 2) the Healthcare Integrity and Protection Data Bank to be used as part of credentialing and peer review. The HCQIA also provided immunity, given restrictions, from damages by peer review participants[7]. However, a case taken to the U.S. Supreme Court in 1988, Patrick v Burget[91] (see Table 2.2), provided further legal guidance.

The Court held that Oregon physicians are not protected by the federal antitrust exemption known as the state action doctrine[92] for their activities on hospital peer review committees[96]. If the peer review process conforms to the standards of the HCQIA and is done in good faith, there are state and federal protections[96, 97], and some authorities maintain that it is difficult to win an antitrust case that challenges peer review of individual competence[98]. Other authorities view the immunity from liability provided by the laws as a way to hide from consequences of bad faith peer review[99]. This controversy continues today.

An essential part of the process of measuring patient quality and safety is medical peer review and event ("805") reporting. Although the terms "peer review" or "peer review body" have been misused by various entity committees (Quality, Risk, Utilization, small "p" peer review versus large "P" peer review), the California code language seems clear about what is a reportable event (see Table 2.4) and what the law defines as a peer review body (see Table 2.6).

Rather than inserting the statute language, the following tables highlight various events in the 805 process. The Business and Professions Code specifies what is to be reported and which entities are to report under Section 805 (see Tables 2.4 to 2.6 and 2.7). Definitions of terms and reporting times are also specified in the code (see Tables 2.4, 2.5, and 2.6).

Table 2.4: What is "805" Reportable (California Business & Professions Code 805)[1]

805 (b) The chief of staff of a medical or professional staff or other chief executive officer, medical director, or administrator of any peer review body and the chief executive officer or administrator of any licensed healthcare facility or clinic shall file an 805 report with the relevant agency within 15 days after the effective date of any of the following that occur as a result of an action of a peer review body:

What is "805" Reportable (California Business & Professions Code 805) [1]
(1) A licentiate's application for staff privileges or membership is denied or rejected for **a medical disciplinary cause or reason;**
(2) A licentiate's membership, staff privileges, or employment is terminated or revoked for **a medical disciplinary cause or reason;**
(3) Restrictions are imposed, or voluntarily accepted, on staff privileges, membership, or employment for a cumulative total of 30 days or more for any 12-month period, for **a medical disciplinary cause or reason;**
805 (c)…Any of the following occur after notice of either an impending investigation or the denial or rejection of the application for **a medical disciplinary cause or reason:**
(1) Resignation or leave of absence from membership, staff, or employment. (2) The withdrawal or abandonment of a licentiate's application for staff privileges or membership. (3) The request for renewal of those privileges or membership is withdrawn or abandoned.
805 (e) An 805 report shall also be filed within 15 days following **the imposition of summary suspension** of staff privileges, membership, or employment, if the summary suspension remains in effect for a period in excess of 14 days.

Table 2.5: Relevant Definitions (California Business & Professions Code 805)[1]

Relevant Definitions (California Business & Professions Code 805)[1]
805 (a) (2)"Licentiate" means a physician and surgeon, doctor of podiatric medicine, clinical psychologist, marriage and family therapist, clinical social worker, or dentist. "Licentiate" also includes a person authorized to practice medicine pursuant to Section 2113 (see Table 2.1).
(4) "Staff privileges" means any arrangement under which a licentiate is allowed to practice in or provide care for patients in a health facility. Those arrangements shall include, but are not limited to, full staff privileges, active staff privileges, limited staff privileges, auxiliary staff privileges, provisional staff privileges, temporary staff privileges, courtesy staff privileges, locum tenens arrangements, and contractual arrangements to provide professional services, including, but not limited to, arrangements to provide outpatient services.
(5) "Denial or termination of staff privileges, membership, or employment" includes failure or refusal to renew a contract or to renew, extend, or reestablish any staff privileges, if the action is based on medical disciplinary cause or reason.
(6) "Medical disciplinary cause or reason" means that aspect of a licentiate's competence or professional conduct that is reasonably likely to be detrimental to patient safety or to the delivery of patient care.

Table 2.6: Peer Review Bodies Defined - Who Reports (CA Business & Professions Code 805) [1]

"Peer review body" includes:

Peer Review Bodies Defined - Who Reports (CA Business & Professions Code 805) [1]
805 (a) (1) (A) A medical or professional staff of any healthcare facility or clinic licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code or of a facility certified to participate in the federal Medicare Program as an ambulatory surgical center.
(B) A healthcare service plan registered under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a disability insurer that contracts with licentiates to provide services at alternative rates of payment pursuant to Section 10133 of the Insurance Code.
(C) Any medical, psychological, marriage and family therapy, social work, dental, or podiatric professional society having as members at least 25 percent of the eligible licentiates in the area in which it functions (which must include at least one county), which is not organized for profit and which has been determined to be exempt from taxes pursuant to Section 23701 of the Revenue and Taxation Code.
(D) A committee organized by any entity consisting of or employing more than 25 licentiates of the same class, that functions for the purpose of reviewing the quality of professional care provided by members or employees of that entity.

Table 2.7: Entities that Report through California 805 Mechanism*

B&P Code 805 & Codes Referenced in B&P Code 805	B&P Code Excerpts
Business & Professions Code 805[1]	Any facility **certified** to participate in the federal Medicare Program as an ambulatory surgical center
Business & Professions Code 805[1]	A committee organized by any entity consisting of or employing **more than 25 licentiates** of the same class that functions for the purpose of reviewing the quality of professional care provided by members or employees of that entity
Health and Safety Code 1200[100]; 1250-1264[101]	Licensed healthcare facilities or clinics; definition of licensed healthcare facilities or clinics; 1204 defines clinics eligible for licensure; 1250 defines as "health facility" means any facility, place, or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer, ...
Health and Safety Code 1340[45]	**Certified** healthcare service plan; Definition of certified healthcare service plan; KKA 1345(f)(1), (f) "Healthcare service plan" or "specialized healthcare service plan" means either of the following: (1) Any person who undertakes to arrange for the provision of healthcare services to subscribers or enrollees, or to pay for or to reimburse any part of the cost for those services, in return for a prepaid or periodic charge paid by or on behalf of the subscribers or enrollees (but there are several exemptions).
Health and Safety Code 1370; 1370.1[1]	Every plan shall establish procedures in accordance with department regulations for continuously reviewing the quality of care, performance of medical personnel, utilization of services and facilities, and costs.
Insurance Code 10133 (aka. Knox-Keene Healthcare Service Plan Act of 1975)[45]	A disability insurer that contracts with licentiates (providers) to provide services at **alternative rates of payment**
Revenue and Taxation Code 23701 tax exempt[102]	Any medical, psychological, marriage and family therapy, social work, dental, or podiatric professional society having as members **at least 25 percent** of the eligible licentiates in the area
Welfare and Institutions Code 14087.95[103]	**Exempts** counties in this category from Health and Safety Code 1340

*partial list

The Business and Professions code specifies the procedure for a “fair hearing” (see Table 2.8) related to 805 reporting. The sections that follow 809.2 in the code further detail the procedures to be followed.

Table 2.8: The 809 Hearing (California Business & Profession Section 809.2[104])

If a licentiate timely requests a hearing concerning a final proposed action for which a report is required to be filed under Section 805, the following shall apply:

B & P Section 809.2
(a) The hearing shall be held, as determined by the peer review body, before a trier of fact, which shall be an arbitrator or arbitrators selected by a process mutually acceptable to the licentiate and the peer review body, or before a panel of unbiased individuals who shall gain no direct financial benefit from the outcome, who have not acted as an accuser, investigator, fact finder, or initial decision maker in the same matter, and which shall include, where feasible, an individual practicing the same specialty as the licentiate.
(b) If a hearing officer is selected to preside at a hearing held before a panel, the hearing officer shall gain no direct financial benefit from the outcome, shall not act as a prosecuting officer or advocate, and shall not be entitled to vote.
(c) The licentiate shall have the right to a reasonable opportunity to voir dire the panel members and any hearing officer, and the right to challenge the impartiality of any member or hearing officer. Challenges to the impartiality of any member or hearing officer shall be ruled on by the presiding officer, who shall be the hearing officer if one has been selected.
(d) The licentiate shall have the right to inspect and copy at the licentiate's expense any documentary information relevant to the charges which the peer review body has in its possession or under its control, as soon as practicable after the receipt of the licentiate's request for a hearing. The peer review body shall have the right to inspect and copy at the peer review body's expense any documentary information relevant to the charges which the licentiate has in his or her possession or control as soon as practicable after receipt of the peer review body's request. The failure by either party to provide access to this information at least 30 days before the hearing shall constitute good cause for a continuance. The right to inspect and copy by either party does not extend to confidential information referring solely to individually identifiable licentiates, other than the licentiate under review. The arbitrator or presiding officer shall consider and rule upon any request for access to information, and may impose any safeguards the protection of the peer review process and justice requires.
(e) When ruling upon requests for access to information and determining the relevancy thereof, the arbitrator or presiding officer shall, among other factors, consider the following: (1) Whether the information sought may be introduced to support or defend the charges. (2) The exculpatory or inculpatory nature of the information sought, if any. (3) The burden imposed on the party in possession of the information sought, if access is granted. (4) Any previous requests for access to information submitted or resisted by the parties to the same proceeding.
(f) At the request of either side, the parties shall exchange lists of witnesses expected to testify and copies of all documents expected to be introduced at the hearing. Failure to disclose the identity of a witness or produce copies of all documents expected to be produced at least 10 days before the commencement of the hearing shall constitute good cause for a continuance.
(g) Continuances shall be granted upon agreement of the parties or by the arbitrator or presiding officer on a showing of good cause.
(h) A hearing under this section shall be commenced within 60 days after receipt of the request for hearing, and the peer review process shall be completed within a reasonable time, after a licentiate receives notice of a final proposed action or an immediate suspension or restriction of clinical privileges, unless the arbitrator or presiding officer issues a written decision finding that the licentiate failed to comply with subdivisions (d) and (e) in a timely manner, or consented to the delay.

The Business and Professions code also defines what is meant by an 821.5 report and how impaired physicians are to be reported (see Table 2.9).

Table 2.9: The Impaired Physician (California Business & Profession Section 821.5[105])

B & P Section 821.5
821.5. (a) A peer review body, as defined in Section 805, that reviews physicians and surgeons, shall, within 15 days of initiating a formal investigation of a physician and surgeon's ability to practice medicine safely based upon information indicating that the physician and surgeon may be suffering from a disabling mental or physical condition that poses a threat to patient care, report to the diversion program of the Medical Board the name of the physician and surgeon under investigation and the general nature of the investigation. A peer review body that has made a report to the diversion program under this section shall also notify the diversion program when it has completed or closed an investigation.
(b) The diversion program administrator, upon receipt of a report pursuant to subdivision (a), shall contact the peer review body that made the report within 60 days in order to determine the status of the peer review body's investigation. The diversion program administrator shall contact the peer review body periodically thereafter to monitor the progress of the investigation. At any time, if the diversion program administrator determines that the progress of the investigation is not adequate to protect the public, the diversion program administrator shall notify the chief of enforcement of the Division of Medical Quality of the Medical Board of California, who shall promptly conduct an investigation of the matter. Concurrently with notifying the chief of enforcement, the diversion program administrator shall notify the reporting peer review body and the chief executive officer or an equivalent officer of the hospital of its decision to refer the case for investigation by the chief of enforcement.
(c) For purposes of this section "formal investigation" means an investigation ordered by the peer review body's medical executive committee or its equivalent, based upon information indicating that the physician and surgeon may be suffering from a disabling mental or physical condition that poses a threat to patient care. "Formal investigation" does not include the usual activities of the well-being or assistance committee or the usual quality assessment and improvement activities undertaken by the medical staff of a health facility in compliance with the licensing and certification requirements for health facilities set forth in Title 22 of the California Code of Regulations, or preliminary deliberations or inquiries of the executive committee to determine whether to order a formal investigation. For purposes of this section, "usual activities" of the well-being or assistance committee are activities to assist medical staff members who may be impaired by chemical dependency or mental illness to obtain necessary evaluation and rehabilitation services that do not result in referral to the medical executive committee.
(d) Information received by the diversion program pursuant to this section shall be governed by, and shall be deemed confidential to the same extent as program records under, Section 2355. The records shall not be further disclosed by the diversion program, except as provided in subdivision (b).

B & P Section 821.5
(e) Upon receipt of notice from a peer review body that an investigation has been closed and that the peer review body has determined that there is no need for further action to protect the public, the diversion program shall purge and destroy all records in its possession pertaining to the investigation unless the diversion program administrator has referred the matter to the chief of enforcement pursuant to subdivision (b).
(f) A peer review body that has made a report under subdivision (a) shall not be deemed to have waived the protections of Section 1157 of the Evidence Code. It is not the intent of the Legislature in enacting this subdivision to affect pending litigation concerning Section 1157 or to create any new confidentiality protection except as specified in subdivision (d). "Pending litigation" shall include Arnett v. Dal Cielo (No. S048308), pending before the California Supreme Court.
(g) The report required by this section shall be submitted on a short form developed by the board. The board shall develop the short form, the contents of which shall reflect the requirements of this section, within 30 days of the effective date of this section. The board shall not require the filing of any report until the short form is made available by the board.
(h) This section shall become operative on January 1, 1997, unless the regulations required to be adopted pursuant to Section 821.6 are adopted prior to that date, in which case this section shall become operative on the effective date of the regulations.

Table 2.10: Public Disclosure - (California Business & Profession Section 2027)

The Business and Professions code defines what the Medical Board can report to the public, what can be reported to entities and agencies, and how long the information is to remain public (see Table 2.10).

B & P Section 2027[106]
2027. (a) On or after July 1, 2001, the board shall post on the Internet the following information in its possession, custody, or control regarding licensed physicians and surgeons: (1) With regard to the status of the license, whether or not the licensee is in good standing, subject to a temporary restraining order (TRO), subject to an interim suspension order (ISO), or subject to any of the enforcement actions set forth in Section 803.1. (2) With regard to prior discipline, whether or not the licensee has been subject to discipline by the board or by the board of another state or jurisdiction, as described in Section 803.1. (3) Any felony convictions reported to the board after January 3, 1991. (4) All current accusations filed by the Attorney General, including those accusations that are on appeal. For purposes of this paragraph, "current accusation" shall mean an accusation that has not been dismissed, withdrawn, or settled, and has not been finally decided upon by an administrative law judge and the Medical Board of California unless an appeal of that decision is pending. (5) Any malpractice judgment or arbitration award reported to the board after January 1, 1993. (6) Any hospital disciplinary actions that resulted in the termination or revocation of a licensee's hospital staff privileges for a medical disciplinary cause or reason. (7) Any misdemeanor conviction that results in a disciplinary action or an accusation that is not subsequently withdrawn or dismissed. (8) Appropriate disclaimers and explanatory statements to accompany the above information, including an explanation of what types of information are not disclosed. These disclaimers and statements shall be developed by the board and shall be adopted by regulation. (9) Any information required to be disclosed pursuant to Section 803.1.
(b) (1) From January 1, 2003, the information described in paragraphs (1) (other than whether or not the licensee is in good standing), (2), (4), (5), (7), and (9) of subdivision (a) shall remain posted for a period of 10 years from the date the board obtains possession, custody, or control of the information, and after the end of that period shall be removed from being posted on the board's Internet Web site. Information in the possession, custody, or control of the board prior to January 1, 2003, shall be posted for a period of 10 years from January 1, 2003. Settlement information shall be posted as described in paragraph (2) of subdivision (b) of Section 803.1. (2) The information described in paragraphs (3) and (6) of subdivision (a) shall not be removed from being posted on the board's Internet Web site. Notwithstanding the provisions of this paragraph, if a licensee's hospital staff privileges are restored and the licensee notifies the board of the restoration, the information pertaining to the termination or revocation of those privileges, as described in paragraph (6) of subdivision (a), shall remain posted for a period of 10 years from the restoration date of the privileges, and at the end of that period shall be removed from being posted on the board's Internet Web site.
(c) The board shall provide links to other Web sites on the Internet that provide information on board certifications that meet the requirements of subdivision (b) of Section 651. The board may provide links to other Web sites on the Internet that provide information on healthcare service plans, health insurers, hospitals, or other facilities. The board may also provide links to any other sites that would provide information on the affiliations of licensed physicians and surgeons.

Summary

The Medical Board of California is charged with protecting the public in regards to medical practice and is responsible for tracking and enforcing the laws that govern medical practice. As the laws and healthcare have increased in complexity, so has the work of the Medical Board. It has become more difficult to ensure that entities are adhering to all the laws and that the laws do not conflict with each other.

Required by law, medical peer review by entities is one of the key mechanisms to monitor patient quality and safety. But peer review as a quality and safety process is being called into question. Professionals have begun to wonder if the "old" way of peer review is sufficient or even necessary any longer. This chapter has provided an overview of some of the history and positive and negative aspects of peer review. Additionally, it has provided alternate strategies used by other states and other entities to monitor quality and safety.

California laws governing medical practice are numerous and complex. Because of this complexity, most hospitals and many physician groups and health plans employ or contract with an attorney or attorneys. The intent of all of these laws has been to protect the public and improve patient care quality and safety. Unfortunately, they have not always worked as intended.

Previous to this study, there has been little empirical evidence on which to base a decision to change the current peer review system. This Peer Review Study is an effort to analyze empirical data to ascertain whether peer review can continue to be relevant in assessing medical care. Chapter III will detail the methodology used in this study to determine whether medical peer review is still appropriate for ensuring patient safety and quality in California medical care entities.

Chapter III: Methodology

Introduction

In this chapter, we provide a detailed explanation of the study methodology in the following format.

Research design includes:

- Study type
- Population
- Sample selection
- Sample size estimates
- Independence of study personnel
- Measurement instruments
- Data collection
- Data analyses

Additionally, we cover criticisms of the study uncovered during the study and the methods used to mitigate them.

Research Design

Study Type

The design of this study is both quantitative and qualitative; it is cross-sectional, retrospective, and descriptive. Since the topic has not been extensively studied in the past, we used multiple data collection methods, including document review, survey, focus groups, site visits, and key informant interviews. All these methods, described in detail later in this chapter, cover the questions required in the 805.2 legislation (see Table 1.1) but in different ways and in different formats. We examined peer review from as many perspectives as possible.

Population

The legislation specified the population for the study. Specifically, Section 805.2 states, "peer review bodies throughout the State, including the role of other related committees of acute care health facilities and clinics involved in the peer review process."[1] We produced a population frame based on the definitions of the eligible entities, as specified in the legislation (see Tables 2.6 and 3.1). We used multiple sources to identify the population of each entity type (see Table 3.1).

Table 3.1: Population Count and Data Source for Study Entities

Entity Type	Population	Sources
Hospitals	366	Office of Statewide Health Planning and Development (OSHPD) 2005[107]
Healthcare plans	51	The California Department of Managed Care 2007[108, 109], California Association of Health Plans[110], Medicare database of health plans
Professional societies	9	Web sites of the state and national professional entities
Medical groups/clinics	123	OSHPD[107], Cattaneo and Stroud Databases and Reports[111], the California Office of the Patient Advocate[112], Medicare database of medical groups

Professional societies are defined in the legislation (see Table 2.6), but we had difficulty estimating a comprehensive population. The legislation lists a number of professions in addition to medicine, so we included those professional entities in our sample. Since the MBC focuses specifically on monitoring the practice of medical doctors and podiatrists, we also included professional entities related to medicine and podiatry.

We defined healthcare facilities as short-term general/general acute care (GAC) hospitals; we defined healthcare plans as full-service medical plans versus dental plans, behavioral health or other system or disease-specific plans. We included both licensed/certified and unlicensed healthcare plans, and we sampled medical groups and clinics that are both licensed/certified and unlicensed/not certified.

We encountered several barriers in obtaining comprehensive lists of health plans, clinics, and medical groups. A list of licensed health plans is available from the Department of Managed Care, but a list of unlicensed health plans is not. We were able to identify some unlicensed health plans using a proprietary Medicare database but were unable to determine why some health plans are not required to be licensed.

Certain primary care and specialty clinics are licensed or certified and lists are available from OSHPD; some clinics are certified by the federal government (e.g., VA and Indian Health). However, there are many clinics that are neither certified nor licensed. Again, we were unable to determine the reasons for why some clinics are neither licensed nor certified by the State. No separate list of "medical groups" exists. Some medical groups can be found in the list of health plans. Others are found in the list of clinics; and some others are found in a proprietary Medicare database.

Another barrier in identifying the population was that health plans and medical groups frequently have multiple aliases (e.g., also-known-as or aka) and doing-business-as (dba) names. Health plans also have multiple names and use different names for various programs within the company, such as the Medicare-specific program, a psychiatric/behavioral health program, or others. An additional complicating factor was that management service organizations (MSO) frequently manage multiple medical groups or clinics and perform various services for them, including peer review. The MSOs may also have other management business, such as a health plan or hospital, or own a health plan or hospital, in addition to managing clinics or medical groups.

The Cattaneo and Stroud Databases maintained jointly by Cattaneo and Stroud and the Pacific Business Group on Health were extremely helpful, as were the reports they produced that were

funded by the California Healthcare Foundation[111]. Therefore, our population is based on the most accurate information available, as well as on the setting-specific parameters mentioned previously. The next section of this chapter details our sampling selection method.

Sample Selection

After establishing the populations, we used the SAS survey select procedure to generate the sample. Following our initial selection, we discovered that a number of the health plans and medical groups were closed and others were duplicates because of dba and aka names. At this point, we discovered the Cattaneo and Stroud databases[111] and were able to obtain the multiple names of medical groups, along with their correct addresses. We searched health plan Web sites to identify the multiple names and multiple program names that were in use, as well as addresses and other contact information. We corrected the populations and again selected our sample. We searched for California chapters of national professional associations for the professions listed in the legislation. There were nine professional societies that were selected to participate.

The selected sample produces an accurate representation of the population of hospitals, health plans, and medical groups in California because 1) the sample adheres to the assumptions in the proportions from a finite population sampling methodology, and 2) we over-sampled both health plans and medical groups by 25% to ensure an adequate number. In the hospital sample, two had changed designation to long-term care (LTC), so we replaced them with matches from their strata. The hospitals were over-sampled by 10% so the sample size remained robust. After the cleaning and replacements, our total sample was n=245 (see Table 3.2).

Table 3.2: Population and Final Sample for Entities

Entity type	Population	Final Sample	% of Population
Hospitals	366	132	36.1%
Healthcare plans	51	28	54.9%
Professional societies	9	9	100.0%
Medical groups/clinics	123	76	61.8%
Total	**549**	**245**	**46.5%**

This final sample was used for Phase I (Document review) and Phase II (Online survey) of the study. Phases III (Site visits) and V (Validation) participants were a 5% sub-sample drawn randomly from within the initial sample (see Table 3.3). Phase IV (Focus groups and Key informant interviews) used invited participants who met certain criteria listed in the proposal: representatives from the four entities, attorneys involved in peer review, physicians who had been reviewed and were reviewers, malpractice company representatives, and patient advocates.

Table 3.3: Sample Counts for Entities by Study Phase

Entity Type	Phase I Document Review	Phase II Survey	Phase III Site Visit	Phase IV Focus Groups*	Phase V Validation (Parts 1 & 2)
Hospitals	132	132	6	*	5/6
Healthcare plans	28	28	1	*	1/1
Professional societies	9	9	0	*	1/0
Medical groups/clinics	76	76	3	*	1/3
Total	**245**	**245**	**10**	*	**8/10**

*Focus group participants and key informant interviewees were invited based on the proposal criteria. These data will be described in Chapter IV.

Sample Size Estimates

Hospitals

We conducted a stratified random selection based on 366 short-term general hospitals in the 14 Health Services Agencies (HSAs) of California[113]. We additionally ensured that the sample was representative of the hospital population in number of staffed beds, rural/urban mix, teaching/non-teaching mix, type of control/ownership, and major hospital systems in California. These variables have previously been shown to have a relationship with hospital patient outcomes and also describe the variability in California medical care delivery. We over-sampled by 10% and selected 132 hospitals.

The sample size was estimated using proportions from a finite population with a bound of .05 (i.e., the sample size is > 5% of the population), a confidence of 95% (i.e., we can be 95% certain that the population parameters are within the confidence intervals), and a predicted population proportion of .50 (i.e., we assume the maximum allowable variance [50%] in the population and use the most conservative [largest] sample [in the language of the social sciences; this produces adequate statistical power to find an effect if an effect is present]).

Table 3.4 provides comparisons of percentages and absolute numbers of the population frames versus sample estimates for each of the strata. The percentages are similar, so we are confident our selection method provides a representative sample of the hospitals in California.

Table 3.4: Comparisons of Hospital Sample Stratified to Population

		Population (n=366)		Sample (n=132)	
Variable	**Level**	**N**	**% of 366**	**n**	**% of 132**
Region	Northern Cal.	31	8.5%	7	5.3%
	Golden Empire	18	4.9%	7	5.3%
	West Bay	14	3.8%	5	3.8%
	North Bay	20	5.5%	7	5.3%
	East Bay	20	5.5%	7	5.3%
	N. San Joaquin	21	5.7%	8	6.1%
	Santa Clara	12	3.3%	5	3.8%
	Mid Coast	11	3.0%	4	3.0%
	Central	30	8.2%	10	7.6%
	Santa Barbara	12	3.3%	5	3.8%
	LA	91	24.9%	36	27.3%
	Inland Empire	33	9.0%	12	9.1%
	Orange County	31	8.5%	11	8.3%
	San Diego/Imperial	22	6.0%	8	6.1%
Bed No.	<120	143	39.1%	53	40.2%
	120-249	128	35.0%	47	35.6%
	250-499	81	22.1%	24	18.2%
	500+	14	3.8%	8	6.1%
Rural/Non	Rural	66	18.0%	22	16.7%
	Non Rural	300	82.0%	110	83.3%
Teach/Non	Teaching	26	7.1%	9	6.8%
	Non Teach	340	92.9%	123	93.2%
Profit/Non	City/County/State	26	7.1%	9	6.8%
	District	46	12.6%	12	9.1%
	Investor	93	25.4%	37	28.0%
	Non Profit	201	54.9%	74	56.1%
System/ Non	CHW	28	7.7%	11	8.3%
	Kaiser	28	7.7%	8	6.1%
	Tenet	20	5.5%	14	10.6%
	Sutter	21	5.7%	10	7.6%
	HCA	5	1.4%	1	0.8%
	Adventist	14	3.8%	4	3.0%
	Non/Other	250	68.3%	84	63.6%

Notes:
Sample frame 2005 Financial Data from OSHPD – Short term general hospitals only.
Simple random selection stratified by HSA.

Health Plans

The sampling method for health plans was a stratified random selection based on strata for HSA (region) and rural versus non-rural. The sampling size was estimated using proportions from a finite population with a bound of .075 (i.e., the sample size is > 7.5% of the population), a confidence of 95% (i.e., we can be 95% certain that the population parameters are within the confidence interval), and a predicted population proportion of .50 (i.e., we assume the maximum allowable variance [50%] in the population and use the most conservative [largest] sample [in the language of the social sciences, this produces adequate statistical power to find an effect if an effect is present]).

Table 3.5 provides comparisons of percentages and absolute numbers of the population frames versus sample estimates for each of the strata. The percentages are similar, so we are confident our selection method provides a representative sample of the health plans in California. We over-sampled by 25% and selected 28 health plans.

Table 3.5: Comparison of Health Plan Sample Stratified to Population

		Population (N=51)		Sample (n=28)	
Variable	**Level**	**N**	**% of 51**	**n**	**% of 28**
Region	01 – Northern California	0	0.0%	0	0.0%
	02 - Golden Empire	3	5.9%	1	3.6%
	03 - West Bay	1	2.0%	1	3.6%
	04 - North Bay	5	9.8%	4	14.3%
	05 - East Bay	8	15.7%	4	14.3%
	06 - North San Joaquin	1	2.0%	0	0.0%
	07 - Santa Clara	3	5.9%	1	3.6%
	08 – Mid Coast	0	0.0%	0	0.0%
	09 - Central	2	3.9%	1	3.6%
	10 - Santa Barbara/ Ventura	2	3.9%	1	3.6%
	11 - Los Angeles County	16	31.4%	11	39.3%
	12 - Inland Counties	1	2.0%	1	3.6%
	13 - Orange County	6	11.8%	2	7.1%
	14 - San Diego/ Imperial	3	5.9%	1	3.6%
Rural/Non	Rural	0	0.0%	0	0.0%
	Non	51	100.0%	28	100.0%

Notes:
Matched health plan address county location to assigned 14 OSHPD regions.
Matched health plan address county location with assigned Rural vs. Urban location based on the 2005 CMS MSA crosswalk.

Medical Groups/Clinics

The sampling method for medical groups was a stratified random selection based on strata for HSA (region), number of physicians in the medical group/clinic, and rural versus non-rural. The sampling size was estimated using proportions from a finite population with a bound of .075 (i.e., the sample size is > 7.5% of the population), a confidence of 95% (i.e., we can be 95% certain that the population parameters are within the confidence interval), and predicted population proportion of .50 (i.e., we assume the maximum allowable variance [50%] in the population and use the most conservative [largest] sample [in the language of the social sciences; this produces adequate statistical power to find an effect if an effect is present]).

Table 3.6 provides comparisons of percentages and absolute numbers of the population frames versus sample estimates for each of the strata. The percentages are similar, so we are confident our selection method provides a representative sample of the medical groups/clinics in California. We over-sampled by 25% and selected 76 medical groups.

Table 3.6: Comparison Medical Group/Clinics Sample Stratified to Population

		Population (N=123)		Sample (n=76)	
Variable	**Level**	**N**	**% of 123**	**n**	**% of 76**
Region	01 – Northern California	2	1.6%	2	2.6%
	02 - Golden Empire	5	4.1%	3	3.9%
	03 - West Bay	5	4.1%	3	3.9%
	04 - North Bay	5	4.1%	2	2.6%
	05 - East Bay	6	4.9%	4	5.3%
	06 - North San Joaquin	4	3.3%	2	2.6%
	07 - Santa Clara	5	4.1%	3	3.9%
	08 – Mid Coast	3	2.4%	2	2.6%
	09 - Central	4	3.3%	2	2.6%
	10 - Santa Barbara/ Ventura	4	3.3%	2	2.6%
	11 - Los Angeles County	41	33.3%	26	34.2%
	12 - Inland Counties	18	14.6%	12	15.8%
	13 - Orange County	10	8.1%	5	6.6%
	14 - San Diego/ Imperial	11	8.9%	8	10.5%
No. of Physicians	1-100	12	9.8%	9	11.8%
	100-500	48	39.0%	31	40.8%
	501+	16	13.0%	7	9.2%
	Unknown	47	38.2%	29	38.2%
Rural/Non	Rural	3	2.4%	3	3.9%
	Non Rural	120	97.6%	73	96.1%

Notes:
Sample frame 2006 California Office of the Patient Advocate (from www.opa.gov site) – Healthcare Quality Report Card Directory and original file sent from OPA contact.

Matched medical group administrative address county location with assigned Rural vs. Urban location based on the 2005 CMS MSA crosswalk.

Two individual primary care clinics were included in the sample for representation.

Professional Societies

We were unable to locate a comprehensive list of professional societies in California. We selected the California chapters of national professional associations/societies representing all the professions listed in the legislation. Additionally, we contacted the California Association of Neurological Surgeons, because they were listed as having filed an 805 in the past, and the California Association of Physician Groups, because they represent physician groups. We contacted a total of nine professional associations/societies and report on the entire population (N=9) rather than a sample.

Independence of Study Personnel

The Legislature and the MBC required that the healthcare consulting firm and the scientists performing the study remained independent of any of the numerous individuals and entities with a vested interest in the peer review process. We maintained this independence in various ways. When we received unsolicited telephone calls and e-mails from entities and individuals asking us questions about the study or offering to assist us with the study or to redesign the methods, we used the following strategies to handle these inquiries:

1. Answered specific questions about the legislation that authorized the study and method.
2. Referred the person to the legislation.
3. Set up a Web site with details and frequently asked questions about the study and referred people to the Web site.
4. Encouraged the person to send messages to the e-mail box listed on the Web site.
5. Encouraged the person to write letters with comments to us.

We consistently informed everyone that the messages and letters would be reviewed near the end of the study and incorporated them in the report or the appendices. Study personnel referred callers or e-mails to Lumetra personnel not involved in the study to allow callers to express their opinions.

In determining the population frame and sample estimates, making decisions, managing refusals, and answering questions and criticisms, we used accepted scientific standards and rigorous methodology in the study. We kept track of all telephone calls and responses, e-mails and responses, and faxes, confirmations, and responses. We responded promptly to participant questions and requests and were flexible in extending deadlines for study phases when possible, while still maintaining the project timeline. We followed up on all calls, e-mails and faxes to ensure the entity an opportunity to participate in the study and maintained the confidentiality of all participants. However, we were required by contract to disclose those entities that declined, did not return contacts, or failed to participate.

We notified these entities that their lack of participation would be noted in the final report. We solicited facts, opinions, and perceptions and attempted to objectively and fairly represent divergent views in this report.

Measurement Instruments

Data were collected using multiple methods to investigate processes of medical peer review, the fair hearing process, and physician physical or mental impairment within the 805 and 821 processes. Phase I of the study was a mailed letter that requested documents from all the sampled entities, including policies, procedures, bylaws, and committee minutes. Phase II of the study was an online structured short-answer survey to staff in specified roles within each participant entity. The survey was designed to specifically address questions raised by the legislation. The survey questions were designed to be analyzed separately, so no psychometric testing was needed.

The survey was piloted twice with internal Lumetra respondents, including physicians, non-physician administrative staff, registered nurses, and statistical analysts. Based on input from these pilot participants, questions were edited for clarity and to make analyses more quantitative.

We created six versions of the survey. Each version was directed to individuals with different peer review roles related within the entities. The peer review committee chair and the non-physician support staff member received the full survey, while people in other positions received a shorter version with questions relevant to their role in the process.

Phase III consisted of site visits to 10 entities as part of the validation process. We created a sub-sample of 5% of the initial sample for site visits to compare documents, minutes, and interviews during an onsite review. Phase IV included focus groups, key informant interviews, and telephone conversations with people with a vested interest in peer review (representatives from the four entities, attorneys involved in peer review, physicians who had been reviewed and were reviewers, malpractice company representatives, and patient advocates). Phase V was the second part of the validation process using a different 5% sub-sample of the initial sample comparing survey results with documents and structured implicit patient record review by physician reviewers.

Data Collection

We followed up with entities by e-mail, telephone, or fax. If they did not respond within four weeks, we made two more attempts to contact them. After three attempts, the entities were listed as "no response" (see Appendix VI: Organizations that Declined or Made No Comment). A number of entities inquired about a penalty if they did not participate, and we cited the legislation as saying, "The independent entity for the study had no authority over them." However, the MBC directed that we list the names of those entities that did not participate in the final report.

Contacts between Lumetra study staff and each entity were maintained by e-mail, telephone, and/or fax with a primary contact (typically a medical staff support person) designated by the CEO or Chief of Medical Staff. In Phase I of the study, we requested all policies, procedures, bylaws, or other documents that described the entities' peer review process. We asked for five years of minutes from any committee whose function was peer review, particularly the decision-making committee such as the Medical Executive Committee (see Appendix I: Study Results and Appendix IV: Structured Review Forms).

In Phase II of the study, we requested that the primary contact forward our request for survey completion to the appropriate individuals within the entity, including peer review committee chairs, reviewing physicians, reviewed physicians, attorneys who represented the entity, attorneys who represented reviewed physicians, and non-physician support staff. We also solicited survey completion by direct mail to physicians who had been reported through the 805 mechanism in the year 2007. As noted earlier, not everyone received the complete survey because not all the questions were relevant to each role (see Appendix II: Survey and Focus Group Questions).

In Phase III of the study, we selected 10 sites from our site visit sample to compare onsite peer review minutes and policies with the documents submitted. The study reviewer spent a day at each site checking documents, including policies and minutes, as well as discussing the entity's processes with the contact person (see Appendix IV: Structured Review Forms). We also made two site visits to the MBC to ask questions and collect data and information (see Appendices I and IV)

In Phase IV, we conducted two telephone focus groups and several key informant interviews between March 15 and April 14, 2008. There were five to seven invited participants in each focus group, with each group of participants representing different roles, including patient safety advocates, attorneys for entities and physicians, health plan executives, medical group executives, and representatives from malpractice companies.

Key informant interviews included patient safety advocates, malpractice companies, health plan executives, and attorneys. One important concern that was raised in the interviews was the possibility of physicians in solo or small practices without hospital privileges never being peer reviewed.

We invited these types of participants based on our contacts with participant entities and their roles in national, state, and local entities (see Appendix II: Survey and Focus Group Questions). In Phase V (Validation) of the study, we performed several activities to allow us to validate the results of the study, including structured implicit patient record reviews by the study medical director (see Appendix IV: Structured Review Forms), comparison of documents with survey results (see Appendix IV), multiple reviewers of all documents and minutes to check reliability, and a review of all data collected and analyzed.

A Web page linked to the Lumetra Web site was created to give an overview of the study, including the specific legislation. The Web page also included frequently asked questions and an e-mail box for anyone who wished to provide feedback about the study. Lumetra staff in a department separate from the study staff monitored the e-mail box, and the e-mails were only examined in the data analysis phase of the study. Appendices I, II, and V contains all study data collection instruments, including the initial document request letter, document review form, minutes review form, all versions of the online survey, MBC visit questions and document review form, focus group/key informant interview questions, and validation request.

Data Analyses

Because of the numerous ways in which data were collected, the issue of unit of analysis for the study was a concern. Peer review is performed at the entity level, so that is our unit of interest. For analyses of the documents and minutes, we aggregated data results to the level of the entity. The data collected via the online survey were not identifiable by individual and are aggregated to the entity type or the respondents' role in the peer review process.

Because of the way some of the survey questions were phrased, we analyzed them by response rather than by role or entity type. The focus group and key informant interview data are analyzed in the context of the role of the participants in relationship to the type of entity or to their role in relationship to peer review. The site visits and other validation methods are analyzed in terms of entity type.

Data analyses encompassed multiple methods beginning with descriptive information of central tendency of the sample. For Phase I, documents were reviewed using a structured format (see Appendix IV: Structured Review Forms); responses were aggregated and quantified using descriptive statistics. The structured format allowed for analyses of comments related to the policies, procedures, and other documents.

Those data are described using qualitative descriptions. Short answer responses from document reviews, surveys, and site visits, focus group/ key informant responses, and structured implicit

review were qualitatively analyzed using 1) an analysis of words (word repetitions, key terms, and key words in contexts); and 2) a careful reading of blocks of texts to identify themes[114].

For Phase II, survey responses were analyzed using measures of central tendency, including mean, median, and mode, measures of proportion, including frequencies and percentages, and measures of variation, including range and standard deviation. We also investigated correlations and means comparisons. Many of the survey questions allowed respondents to provide comments. These comments are described qualitatively in the results section, and the actual comments appear in Appendix IX: Comments About Study.

For Phase III (Site Visits), data were analyzed using content analysis of the structured reviews (see Appendix IV: Structured Review Forms) and by quantifying data as possible. In Phase IV, focus groups and key informant interviews were also analyzed using content analysis based on the broad questions that were asked (see Appendix II: Survey and Focus Group Questions). Phase V (Validation) data were analyzed descriptively using the comparisons (survey responses and documents) and structured implicit chart review (reviewing actions taken by the entity).

Study Criticisms

Through several sources, we heard about criticism of the study while it was in progress. Below, we describe the types of criticism/concern of which we are aware and list underneath the methods (responses) we used to counter or mitigate any negative effects.

1. Lumetra's ability to maintain independence during the study
   a. Lumetra has no vested interest in the results of the study.
   b. The sampling method was random, blinded to the researchers, and generated by computer.
   c. A Web site was created to explain the study and allowed people to submit comments.
   d. A department separate from the study researchers monitored the site and only provided the comments to the researchers at the end of the study.

2. Funding for Lumetra to conduct this study (i.e., to "do it right")
   Although both money and time were limited, we made use of both by setting deadlines and moving through the study requirements in a consistent manner.

3. Study presumption that there is failure in the 805 reporting method
   a. Although there appears to be a small number of 805 reports per California population, one of the purposes of the study was to investigate the issue of appropriate reporting.
   b. As an independent contractor, Lumetra was in the position of being objective about the data and did not form premature assumptions.

4. Information about cases not reported and reasons why to be used against physician or hospital
   a. In order to understand whether appropriate 805 reporting is being done, it is necessary to understand decisions that are made not to report an event.
   b. The legislation guaranteed that the information would not be used against a hospital or a physician.

5. The burden of and expense of study requests (e.g., five years' worth of cases too many to send to Lumetra).
   a. The entities' policies dictate the number of cases reviewed and the peer review committee minutes format.
   b. Entities with the least electronic record capability were the most significantly impacted.

c. We asked for the minimum data to answer the study questions; we also extended numerous deadlines for entities in all phases of the study.

6. Document requests in violation of Evidence Code 1157
   B&P 805.2 made clear that the documents provided to the study team would not be "discoverable."

7. MBC requirement to provide a list of entities that declined or did not participate
   Lists of entities that declined or did not participate are in Appendix VI: Organizations that Declined or Made No Comment, of this final report, as required by MBC.

8. Superficial and biased survey questions would produce sensational results but no meaningful data (see Appendices II and IV)
   a. The survey was one method of allowing a large number of individuals to have input into the study.
   b. The questions attempted to uncover complex and difficult issues.
   c. Individuals were invited to add comments or write e-mails or letters to Lumetra to provide additional information and for inclusion in the study.
   d. Many did provide additional comments, and they are included in Appendix IX: Comments About Study.

9. Awkward wording of survey questions (see Appendices II and IV)
   a. The questions were reviewed numerous times before the survey went online to try to insure they were clear and concise.
   b. The content of the legislation is complex and questions and absolute answers were difficult to construct.
   c. The wording of some of the questions is a limitation of this part of the study.
   d. We also offered all participants the option of writing comments and letters.

10. Closed hospitals surveyed by Lumetra
    a. Requests were sent to one hospital that had closed between the creation of the database and the beginning of the study; two others had converted from a general acute care hospital to long term care; a third error in our data led to a letter meant for a health plan being sent to one of their older closed hospitals.
    b. We corrected all these errors in our data.

11. People not notified about the survey
    a. Each entity had a primary contact person.
    b. The online survey Web link was forwarded to the contact person.
    c. We contacted physicians who had been the subject of an 805 report and invited them to complete a survey.
    d. All the people who had emailed or called were encouraged to comment through our study Web site or direct mail surveys.

12. The necessity of asking whether MDs are paid or not for peer review
    One of the study requirements is to estimate the cost of peer review.

13. The inclusions of questions suggesting that an elite group controls hospital privileges and uses peer review for political reasons, such as the elimination of competitors, ethnic minorities, persons for whom English is a second language, and females
    a. These questions were required by the legislation.
    b. Some individuals were offended that these questions were asked.
       Other individuals were grateful that these questions were asked.

14. The term “peer review process” not defined by law, and Lumetra staff refusal to elaborate on the law (some entities say “little peer review” and others, “big peer review”)
    a. The term peer review is used to mean many things.
    b. This study was designed to study medical peer review performed by medical doctors.

15. Lumetra inability to define peer review body or clarify more specifically what documents would be required
    a. The study team used the definitions in the law to try to clarify terms.
    b. The team attempted to be explicit about what was required (five years of minutes from peer review committees).

16. Study request for information protected by the Lantermann-Petris-Short Act
    a. The team did not ask for protected mental health information, rather we asked for the process of dealing with physicians who are impaired.
    b. We also asked that neither patients nor physicians be identified to us.

17. Lack of a representative sample with only 10 site visits conducted
    a. The primary way the study was designed to answer questions was through a review of policies, procedures, bylaws, and committee minutes.
    b. The initial proposal did not call for site visits; however, we added them because some entities were reluctant to provide peer review committee minutes.
    c. The sampling strategy was presented earlier in the chapter and demonstrates that our sample is representative.

18. Only few events were found that should have, but did not, trigger an 805 report
    a. Generally, we found that entities followed the letter of the law as they understand it.
    b. We contacted organizations that had questionable events and suggested they review the specific issue we found.

19. Creation of peer review policies by entities after requested by Lumetra
    Based on the documents reviewed and telephone and e-mail communication with the entities’ staff members, we did not find evidence to support this concern.

Summary

This chapter has provided detail about the research study design, measurement instruments, data collection, and data analyses. The study is retrospective, cross-sectional, and descriptive. The sampling method was stratified random selection. Data collection methods included document review, survey, site visits, focus group/key informant interviews, and study validation. We are confident that our sample is representative of healthcare entities in California based on the rigorous sampling and comparison of respondents and non-respondents.

From the study onset, there was resistance and anxiety from entities that were included in the sample. Although we attempted to alleviate the anxiety by providing explanations and flexible deadlines and listening to concerns, a number of entities and their attorneys have criticized the study methodology during the study. We have endeavored to articulate this criticism and the ways in which we mitigated any negative effects.

Chapter IV: Results

This chapter first presents a description of the sample, including the study respondents and non-respondents. Next, we detail the study findings and list the results from the various data collection methods under the relevant study requirements as specified in the B & P Code Section 805.2 (see Table 1.1). We conclude with the measures taken to validate the study.

Sample Description

The overall study response rate was 75.6%. Even though every entity did not respond to all the study phases, this responses rate is very good, given that survey response rate estimates of 50% are considered good[115] (see Table 4.1). The majority of entities sent some documents and participated in the survey. However, the peer review committee minutes (see Table 4.5) were omitted by many entities.

As required by the MBC, a list of entities that declined or did not respond to our communication, including the e-mail and letters detailing the reasons for non-participation, is in Appendix VI: Organizations that Declined or Made No Comment. The main reason offered was a lack of resources to gather the information. The next most common reason was per the advice of an attorney.

Figures 4.1 and 4.2 are graphic representations of the selected sample and the final participants in relationship to the location of the entities within the State. It is clear from these figures that the sample and the participants represent all geographic regions of California.

Figure 4.1: Map of Study Sample

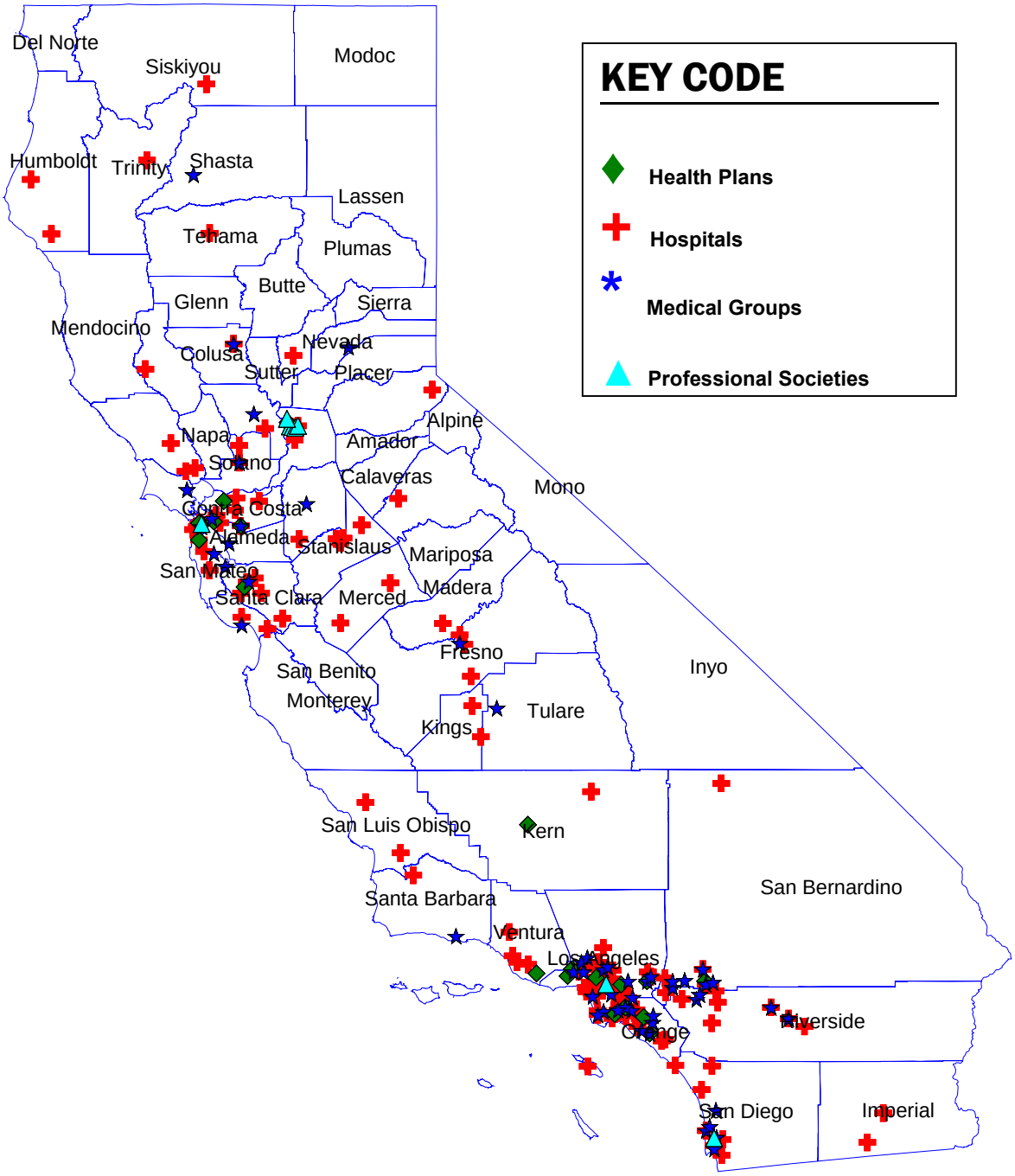


Figure 4.2: Map of Study Participants

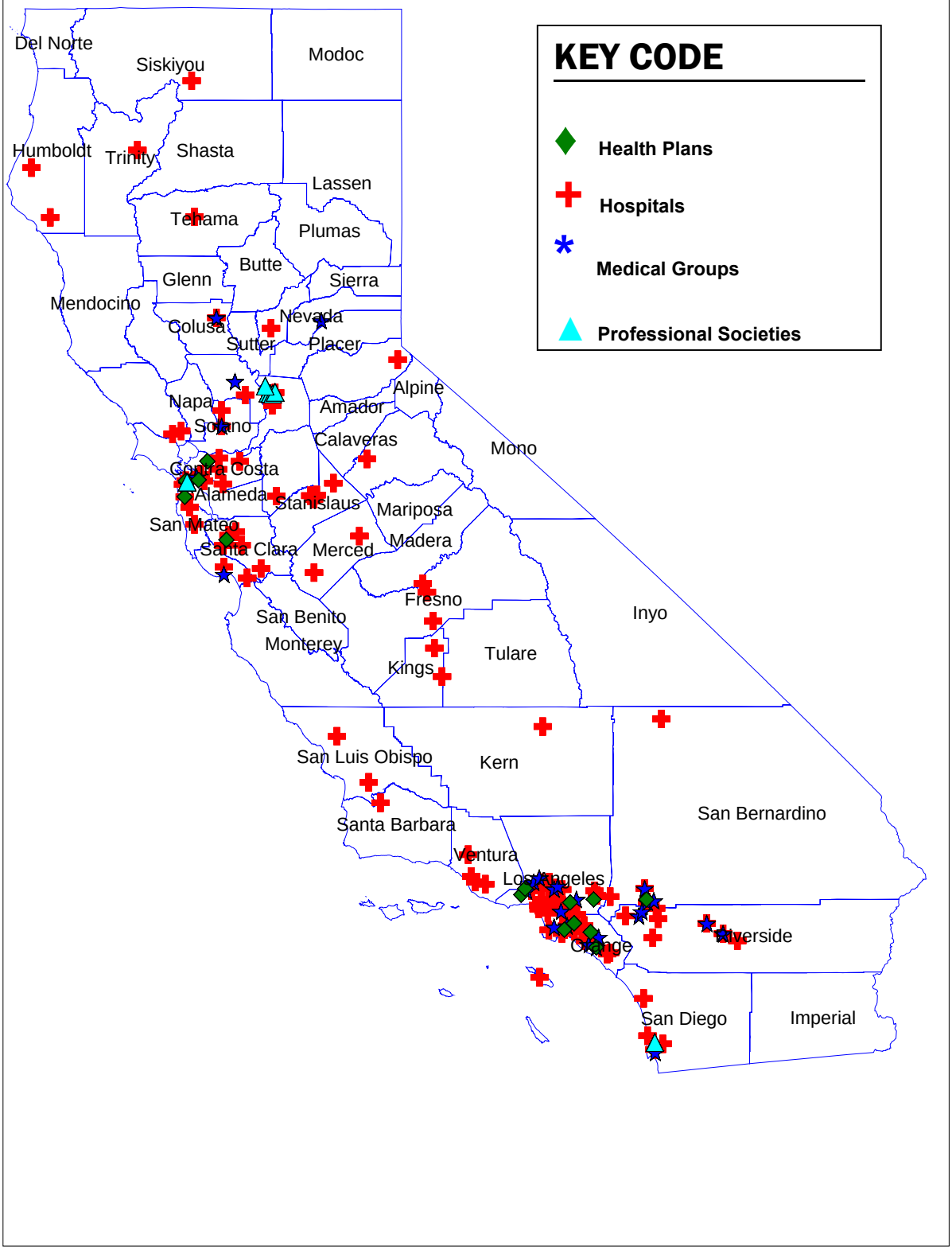


Table 4.1: Entity Participation by Study Phase

Entity type	Final Sample n (% of sample)	Participation in Study n (% of sample)	Declined or Did Not Participate n (% of sample)	Phase I Document Submits n (% of sample)	Phase II Survey n (% of sample)	Phase III* Site Visits	Phase IV** Focus Groups	Phase V Validation Parts 1 & 2
Hospitals	132 (100%)	117 (88.6%)	15 (11.4%)	109 (82.6%)	70 (53.0%)	6	**	5/6
Healthcare plans	28 (100%)	22 (78.6%)	6 (21.4%)	21 (75.0%)	13 (46.4%)	1	**	1/1
Professional Societies	9 (100%)	8 (88.9%)	1 (11.1%)	8 (88.9%)	1 (11.1%)	0	**	1/0
Medical groups/clinics	76 (100%)	38 (50.0%)	38 (50.0%)	34 (44.7%)	23 (30.3%)	3	**	1/3
Total	**245 (100%)**	**185 (75.5%)**	**60 (24.5%)**	**172 (70.2%)**	**107 (43.7%)**	**10**	**	**8/10**

*Two sites included two entities each; one site visit included two hospitals, and one site visit included one medical group and one hospital. This occurred because one department in an entity performed quality/peer review for more than one entity.
**Focus group participants and key informant interviewees were invited based on specific characteristics described in Chapter IV.

As Tables 4.1, 4.2, 4.3, and 4.4 illustrate, the non-respondents were distributed randomly throughout our strata and did not differ from the respondents. Because of the concern expressed about the generalizability of the findings to the population, we took the extra precaution of comparing the population, sample, and participants by strata percentages. Although some of the information is redundant from previous tables, it is important to demonstrate the fact that the participants are sufficiently representative of the sample and the sample is representative of the population (see Tables 4.2, 4.3, and 4.4).

When reviewing these percentages, it becomes apparent that the participating entities are representative of both the overall population of California and of the individual strata from which they were drawn. Therefore, we are confident that the sample is generalizable to the State and to the various regions in the State. In addition to highlighting the generalizability of the sample to the population, the tables display sample characteristics

Table 4.2: Comparison of Hospital Participants Stratified to Sample

		Population (N=366)		Final Sample (n=132)		Study Participants (n=117)	
Variable	**Level**	**N**	**%**	**n**	**%**	**n**	**%**
Region	01 – Northern California	31	**8.5%**	7	**5.3%**	6	**5.1%**
	02 - Golden Empire	18	**4.9%**	7	**5.3%**	7	**6.0%**
	03 - West Bay	14	**3.8%**	5	**3.8%**	4	**3.4%**
	04 - North Bay	20	**5.5%**	7	**5.3%**	6	**5.1%**
	05 - East Bay	20	**5.5%**	7	**5.3%**	7	**6.0%**
	06 - North San Joaquin	21	**5.7%**	8	**6.1%**	8	**6.8%**
	07 - Santa Clara	12	**3.3%**	5	**3.8%**	5	**4.3%**
	08 – Mid Coast	11	**3.0%**	4	**3.0%**	4	**3.4%**
	09 - Central	30	**8.2%**	10	**7.6%**	9	**7.7%**
	10 - Santa Barbara/ Ventura	12	**3.3%**	5	**3.8%**	5	**4.3%**
	11 - Los Angeles County	91	**24.9%**	36	**27.3%**	31	**26.5%**
	12 - Inland Counties	33	**9.0%**	12	**9.1%**	11	**9.4%**
	13 - Orange County	31	**8.5%**	11	**8.3%**	10	**8.5%**
	14 - San Diego/ Imperial	22	**6.0%**	8	**6.1%**	4	**3.4%**
Bed No.	<120	143	**39.1%**	53	**40.2%**	47	**40.2%**
	120-249	128	**35.0%**	47	**35.6%**	41	**35.0%**
	250-499	81	**22.1%**	24	**18.2%**	22	**18.8%**
	500+	14	**3.8%**	8	**6.1%**	7	**6.0%**
Rural/Non	Rural	66	**18.0%**	22	**16.7%**	20	**17.1%**
	Non Rural	300	**82.0%**	110	**83.3%**	97	**82.9%**
Teach/Non	Teaching	26	**7.1%**	9	**6.8%**	7	**6.0%**
	Non Teaching	340	**92.9%**	123	**93.2%**	110	**94.0%**
Profit/Non	City/County/State	26	**7.1%**	9	**6.8%**	6	**5.1%**
	District	46	**12.6%**	12	**9.1%**	10	**8.5%**
	Investor	93	**25.4%**	37	**28.0%**	33	**28.2%**
	Non Profit	201	**54.9%**	74	**56.1%**	68	**58.1%**
System/Non	CHW	28	**7.7%**	11	**8.3%**	11	**9.4%**
	Kaiser	28	**7.7%**	8	**6.1%**	8	**6.8%**
	Tenet	20	**5.5%**	14	**10.6%**	14	**12.0%**
	Sutter	21	**5.7%**	10	**7.6%**	8	**6.8%**
	HCA	5	**1.4%**	1	**0.8%**	1	**0.9%**
	Adventist	14	**3.8%**	4	**3.0%**	4	**3.4%**
	Other	250	**68.3%**	84	**63.6%**	71	**60.7%**

Table 4.3: Comparison of Health Plan Participants Stratified to Sample

		Population (N=51)		Proposed Sample (n=28)		Study Participants (n=22)	
Variable	**Level**	**N**	**%**	**n**	**%**	**n**	**%**
Region	01 – Northern California	0	**0.0%**	0	**0.0%**	0	**0.0%**
	02 - Golden Empire	3	**5.9%**	1	**3.6%**	1	**4.5%**
	03 - West Bay	1	**2.0%**	1	**3.6%**	0	**0.0%**
	04 - North Bay	5	**9.8%**	4	**14.3%**	3	**13.6%**
	05 - East Bay	8	**15.7%**	4	**14.3%**	3	**13.6%**
	06 - North San Joaquin	1	**2.0%**	0	**0.0%**	0	**0.0%**
	07 - Santa Clara	3	**5.9%**	1	**3.6%**	1	**4.5%**
	08 - Midcoast	0	**0.0%**	0	**0.0%**	0	**0.0%**
	09 - Central	2	**3.9%**	1	**3.6%**	0	**0.0%**
	10 - Santa Barbara/ Ventura	2	**3.9%**	1	**3.6%**	0	**0.0%**
	11 - Los Angeles County	16	**31.4%**	11	**39.3%**	11	**50.0%**
	12 - Inland Counties	1	**2.0%**	1	**3.6%**	1	**4.5%**
	13 - Orange County	6	**11.8%**	2	**7.1%**	2	**9.1%**
	14 - San Diego/ Imperial	3	**5.9%**	1	**3.6%**	0	**0.0%**
Rural/Non	Rural medical group	0	**0.0%**	0	**0.0%**	0	**0.0%**
	Non Rural medical group	51	**100.0%**	28	**100.0%**	22	**100.0%**

Table 4.4: Comparison of Medical Group Participants Stratified to Sample

		Population (N=123)		Sample (n=76)		Participants (n=38)	
Variable	**Level**	**N**	**%**	**n**	**%**	**n**	**%**
Region	01 – Northern California	2	**1.6%**	2	**2.6%**	2	**5.3%**
	02 - Golden Empire	5	**4.1%**	3	**3.9%**	3	**7.9%**
	03 - West Bay	5	**4.1%**	3	**3.9%**	2	**5.3%**
	04 - North Bay	5	**4.1%**	2	**2.6%**	1	**2.6%**
	05 - East Bay	6	**4.9%**	4	**5.3%**	2	**5.3%**
	06 - North San Joaquin	4	**3.3%**	2	**2.6%**	0	**0.0%**
	07 - Santa Clara	5	**4.1%**	3	**3.9%**	0	**0.0%**
	08 - Midcoast	3	**2.4%**	2	**2.6%**	1	**2.6%**
	09 - Central	4	**3.3%**	2	**2.6%**	0	**0.0%**
	10 - Santa Barbara/ Ventura	4	**3.3%**	2	**2.6%**	0	**0.0%**
	11 - Los Angeles County	41	**33.3%**	26	**34.2%**	14	**36.8%**
	12 - Inland Counties	18	**14.6%**	12	**15.8%**	9	**23.7%**
	13 - Orange County	10	**8.1%**	5	**6.6%**	3	**7.9%**
	14 - San Diego/ Imperial	11	**8.9%**	8	**10.5%**	1	**2.6%**
Medical Group Size	1-100	12	**9.8%**	9	**11.8%**	6	**15.8%**
	100-500	48	**39.0%**	31	**40.8%**	14	**36.8%**
	501+	16	**13.0%**	7	**9.2%**	3	**7.9%**
	Unknown	47	**38.2%**	29	**38.2%**	15	**39.5%**
Rural/ Non Rural	Rural medical group	3	**2.4%**	3	**3.9%**	3	**7.9%**
	Non Rural medical group	120	**97.6%**	73	**96.1%**	35	**92.1%**

Findings

The Process of Peer Review

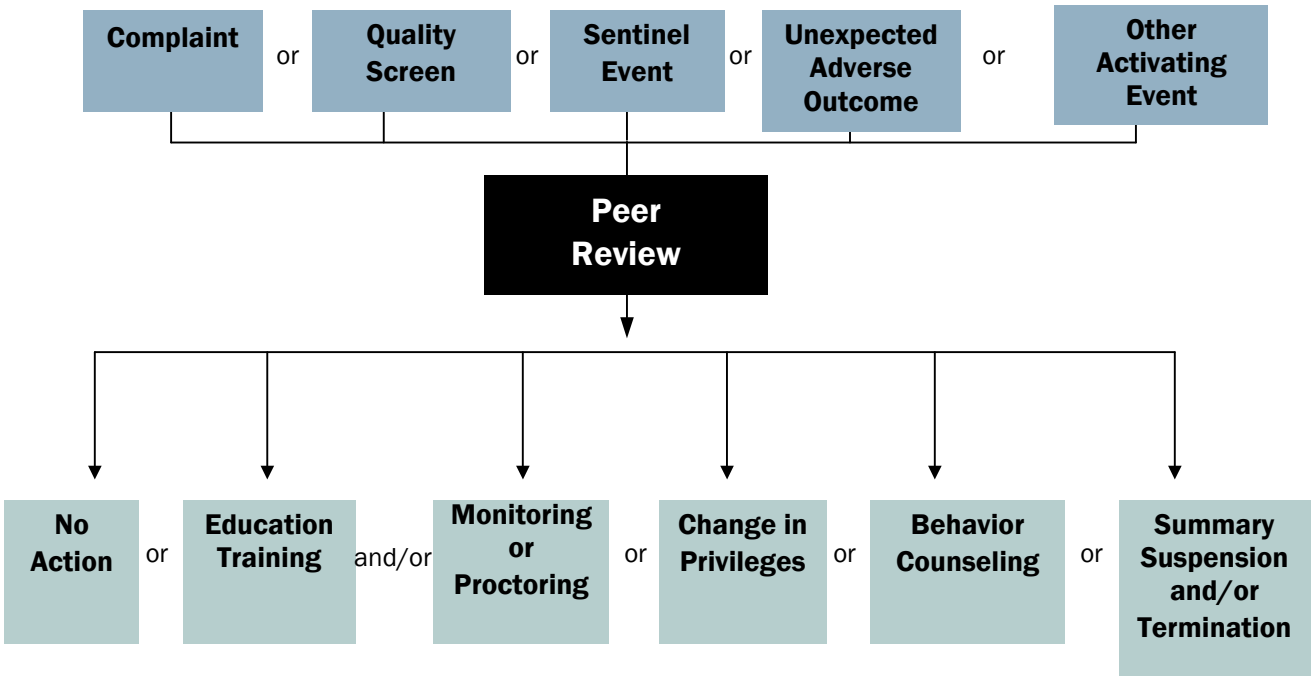
As explained earlier, medical peer review is used to determine whether medical care administered by physicians meets the standards set by an entity to ensure quality and safety in the entity's patient populations. If it does, the physician is allowed to continue to be affiliated with the entity and to treat patients within the context of the entity.

The determination of whether or not physicians' actions meet the standards set by the entity is made by "peer" medical physicians within the entity. Although most medical care entities develop policies and procedures that adhere to standards set by accrediting agencies or professional entities, the entity documents we reviewed indicated that standards within an entity are set by medical staff members who are affiliated with the entity. Oversight by State and federal licensing and credentialing entities provides direction as to standards that should or must be included, but the medical staff members in the entities make the final decisions.

Figure 4.3 displays the peer review process we typically found described in entity documents. Entity peer review policies indicated that there are numerous ways to trigger the peer review process, including routine quality screens done at the medical department level or in various committees in the entity. Peer review also may be triggered by a complaint, an unusual event, a sentinel event, or other methods.

The outcome of peer review likewise is varied. The peer review process may determine that there is no action needed, education may be needed, monitoring is required, or more severe action is needed, including summary suspension or termination. But what actually happens in the "black box" of peer review?

Figure 4.3: The California Peer Review Process



The remainder of this chapter presents evidence to answer this “black box” /"peer review" question. The precipitating events and outcomes of peer review in different entities are highly variable and specific to each entity. The following section details the findings from our document review and comments from participant individuals. The findings are organized by their relevance to the specific requirements of 805.2 legislation.

Requirement I: A comprehensive description of the various steps and decision makers in the peer review process as it is conducted by peer review bodies throughout the State, including the role of other related committees of acute care health facilities and clinics involved in the peer review process.

Document Review

To respond to Requirement I, we used document review and on-line surveys. We requested documents related to peer review activities from all selected entities (see initial request in Appendix I: Study Results), including policies, procedures, bylaws, charters, and minutes from quality, well being, peer review, or department committees for the time period 2002-2007.

We were seeking details of the entities’ processes of peer review and event reporting decision-making. We made no fewer than three attempts to contact each entity asking for these documents (see Table 4.3) and responded to over 400 telephone, e-mail, and fax inquiries about the project.

Based on comments from participants and documents from entities, we learned that the term “peer review” is used to mean different activities in different entities. However, in this study, we only studied and reported on medical peer review done by medical peers. Peer review committee minutes and activities are protected from discovery by California Evidence Code 1157[55], and the peer review committee meetings are typically closed to anyone other than recording staff and peers.

Policies and procedures indicate that peers may be physicians in the entity, physicians of a specific specialty or expertise, or physicians external to the entity (external review) depending on the event to be reviewed. The entities make an attempt to create peer review activities that are unbiased and objective, and focus first on remediation rather than disciplinary action whenever possible. However, most medical groups are small enough or the specialty is small enough that it is impossible for reviewers to be unaware of the identity of the physician being reviewed.

Credentialing of a physician by an entity can be thought of as the initial peer review interaction. The physician applies for privileges and presents credentials and other documents testifying to his/her qualifications. It is incumbent upon the physician to convince the entity that he/she is qualified to be a member of the medical staff. Medical executive bylaws that were reviewed indicate that the medical staff members make a determination about the application for privileges in the entity and either grant or deny the right to practice in the entity.

Re-credentialing of each physician who is granted privileges is done on a periodic basis in each entity. In re-credentialing, if the membership is terminated or restricted, it is incumbent upon the entity to demonstrate that the physician is no longer qualified to be a member of the medical staff.

Based on policy, procedure, and minutes review, peer review activities occur between the periodic re-credentialing of physicians. A peer review can be triggered in a number of ways (see Figure 4.3), but most frequently it is part of the quality/safety/risk process of an entity. Policies indicated that it may be started in various committees such as quality assurance/improvement, risk management,

utilization review/management committees, but it is frequently begun in a medical staff department committee.

Most participant entities routinely screen a certain percentage of patient records to check for evidence of substandard care that may be related to system problems, violations of discipline-specific standards, or violation of entity policies and procedures. A complicating factor in understanding the initiation of medical staff peer review issues is that the entity committee minutes indicated that all types of risk management events and actions are combined and discussed in "peer review" committees. Additionally, based on our review of committee minutes, medical staff committees often combine risk management/peer review issues with mundane issues related to running the business of the entity, such as fee increases, other financial issues, and other concerns.

The usual start of the peer review process in many organizations is when a non-physician support staff member (frequently a nurse) performs an explicit review (a review of the record using a structured format and procedure) of a medical record. If the non-physician support staff member using explicit review finds records that "fall outside the screen" (outside the standards of care for the entity), or if there are events that are questionable, the staff member forwards the record for review to the chair of a peer review committee or to the entire committee, depending on the policy and procedure. The record may then be forwarded to a higher-level committee of medical staff for more intensive medical staff review and evaluation.

Depending on the size and structure of the entity and the committees, the more intensive review may be at the departmental level, the medical executive committee, or other responsible medical staff groups, or any variation of these. If there is substantial deviation from the standard of care, the patient record follows the entity procedure and is eventually reviewed by the highest-level medical committee for decision-making and determination if any action should be taken against the physician.

As indicated in Figure 4.3, and based on our review of policies and procedures, events other than routine screening of records also can trigger peer review. Depending on the severity, as determined by the person who learns of the event and those persons who become involved in reviewing the details of the event, the peer review process can move quickly. Generally, however, our review of committee minutes demonstrated that the process is very lengthy involving months or years of re-review, review of more records, interviews with the physician, and/or other investigation methods within the entity.

The medical executive/decision making committee may require a focused review, which is a larger sample of patient records for targeted review of the physician in question. The focused review may require other physicians in the entity to review records and may require discussions about what the standard of care is for the particular event. If there are only a few physicians in the entity with limited expertise in the area of the event, an external review may be initiated. A contracted expert outside the entity conducts an external review, which may further delay any potential action taken as a result of the event.

There are many steps in the peer review process that allow variation. The entity policy defines what is reviewed, but typically a non-physician hospital staff/committee support employee is responsible for the initial review, maintenance of the quality, safety, risk, or credentialing processes and committees minutes, and tracking of events and physician behavior over time. To summarize, there is variation in what is subject to peer review, determined not only by the procedure that initiates peer review, but also by the individual support staff member and committee chairs' knowledge and tenacity in tracking events and physicians over time.

As indicated in Chapter III, we reviewed documents and minutes using a structured format (see Appendix IV: Structured Review Forms) that included assessment of whether:

- A bylaws template was used.
- The process for quality and safety assessment was outlined in bylaws or policies.
- There was a method for a fair hearing.
- There was a process for dealing with impaired physicians.

We also assessed whether the entity had a tracking system that allowed for systematic follow-up for events that potentially would be reported to the MBC, and whether the overall quality/safety/risk management program was organized and easy to understand and follow. Table 4.5 presents some of the findings of our structured review. Rather than submitting minutes, some entities provided a summary of an event to be used as an example of how the entity handled reporting through 805 or deciding not to report.

Table 4.5: Summary of Documents Submitted by Entity Type

Entity Type	Number in Final Sample	Number Submitting Any documents	Number Submitting No Minutes	Number Submitting Any Minutes	Number Submitting Five years Minutes	Number Submitting < Five Years Minutes	Number Providing Event Summary
Hospitals	132	109	104	28	17	11	30
Healthcare plans	28	21	12	16	14	2	11
Professional societies	9	8	9	0	0	0	0
Medical groups/ clinics	76	34	52	24	19	5	6
Total	**245**	**172**	**177**	**68**	**50**	**18**	**47**

Professional societies behave differently than the other three entity types. Of the eight that responded to our document request, four stated that they did not perform peer review and the other four reported that they were rarely involved in peer review. Of the four who were involved in peer review, three have policies and procedures but report any 805s to a professional board rather than the MBC. The remaining entity only accepts complaints about its members and refers other complaints to the MBC, so professional societies/entities have only minor role in the process of peer review.

One hundred-fifty entities (61.2% of 245) described the peer review process used in the entity through policies, procedures, or bylaws. Ninety-seven hospitals (78.5% of 132) used a template for medical staff bylaws, which provided a systematic way to include all the required elements necessary for description of peer review, and the disciplinary process that might occur (see Appendix IV: Structured Review Forms). Fifty-five and a half percent of the entities (136 of 245) described the 805 reporting process, and 55.1% (135 of 245) described the due process/fair hearing procedure. However, only 21.2% (52 of 245) mentioned or described the process for dealing with an impaired physician.

One third (33.1% of 245) of the entities used an event category or rating system based on severity, and a similar percentage (31% of 245) had a rating system for actions taken as a result of an event.

43.3% of the 245 entities had explicit definitions of events that initiated peer review and actions that resulted. Using a scale of 0 to 5 with 0 being no definitions, 1 being the poorest definitions, and 5 being the best definitions, as judged by the research team, entities scored an average of 1.2 (sd=1.7) in having explicit definitions of different categories of events or actions. Hospitals (mean=2.0 [1.8]) and health plans (mean=1.0 [1.7]) had the most explicit definitions, while medical groups (mean=.92 [1.4]) and professional groups (mean=.89 [1.8]) had less specific definitions.

Tracking events over time is an essential part of peer review because of the length and complexity of internal investigations. We scored the entities on whether the tracking systems were comprehensive based on evidence in minutes, policies, and procedures using a 0 (no evidence of tracking) to 5 (most comprehensive) scale based on the judgment of the research team. We determined "comprehensiveness" by reviewing policies and procedures to see if there were specific time frames specified for reviews and evaluating minutes to see if the policies were then followed.

We found that entities scored 0.5 (sd=1.0) overall with health plans averaging .89 (sd=1.6); hospitals averaged .82 (sd=1.5), and medical groups averaged .28 (sd=.9). None of the professional societies provided documents that indicated if they had a tracking system for peer review cases.

Based on the minutes reviewed in submitted documents and site visits, we found that entities generally follow their own policies and procedures related to peer review with the most common policy violation being the length of time it takes to complete an investigation and review. But tracking systems are limited and difficult to follow, and there is a great deal of variation in the specificity of policies and procedures about events that are investigated.

Online Survey

Information gleaned from the surveys is discussed next. One hundred-fifteen entities responded to the online survey from 245 eligible entities (see Table 4.6).

Table 4.6: Online Survey - Entity Response Rate

	Returned Survey	Eligible	Entity Response Rate
Entities	115	245	46.9%

Twenty percent of respondents were chairs of peer review committees, 21.1% were physician reviewers, 8% were physicians who had been reviewed, 41.1% were non physician support staff, 8.6% were attorneys representing entities, and 1.1% were attorneys representing a reviewed physician (see Table 4.7). Each of the four entity types was represented in the survey respondents; 62.9% were hospitals (see Table 4.8).

Table 4.7: Number of Online Survey - Individual Responses by Entity Type and Individual Role in Entity

	Entity Type				Total	%
Role	Hospital	Health Plan	Medical Group	Professional Society		
Peer Review Chair	44	7	15	4	70	20.0%
Physician Reviewer	30	21	21	2	74	21.1%
Physician Reviewed	21	1	5	1	28	8.0%
Non Physician Staff	97	8	32	7	144	41.1%
Attorney Representing Entity	25	0	2	3	30	8.6%
Attorney Representing Physician	3	0	1	0	4	1.1%
Total	**220**	**37**	**76**	**17**	**350**	**100.0%**

Table 4.8: Number of Online Survey - Responses by Entity Type

Entity Type.	n	%
Healthcare Plan	37	10.6%
Hospital	220	62.9%
Medical Group	76	21.7%
Professional Society	17	4.9%
Total	**350**	**100.0%**

Because we used six different versions of the study, we had varying numbers of potential or eligible respondents for each question. We provide the number of persons **eligible** to answer the question. In order to give an accurate representation of missing data, we also provide the number of respondents used as the denominator of the % when we report percentages.

The most common name of the decision-making/final authority committee was the Medical Staff Executive committee, followed by the Peer Review committee and Quality or Quality Improvement committee. The average number of members on the decision-making committee was 16 with an additional four non-physician hospital staff support members. Committees averaged eight different medical specialties represented and three other disciplines (see Table 4.9). Internal medicine, family practice, and surgery were the most frequently mentioned specialties on the committee and the usual length of time a member serves on a committee is for two or more years (see Table 4.10).

Table 4.9: Online Survey - Peer Review Body Composition
(214 eligible respondents)

What is the Composition of the Peer Review Body?	n	Mean	sd*
Total number (#) of members	137	16.4	9.2
Number (#) of committee members who are non-physician staff	140	3.8	3.2
Number (#) of disciplines represented besides medicine (nursing, medicine, pharmacy, etc)	135	2.8	3.7
Number (#) of different medical specialties represented (surgery, pediatrics, etc)	134	7.7	4.6
Number (#) of committee members who are generalists	120	3.4	5.9

*sd - standard deviation

Table 4.10: Online Survey - Peer Review Body Length of Term
(70 eligible respondents; 52 actual respondents; percentages based on a denominator of 52)

What is the usual term for each member who serves on the peer review body?	n	%
1 year	4	7.7%
2 years	14	26.9%
More than 2 years	24	46.2%
Other (please specify term)	10	19.2%
Total	**52**	**100%**

The decision-making committees reported multiple responsibilities, including managing overall quality of care issues, complaint/sentinel event investigation, monitoring physician practice and practice patterns, determining disciplinary action, and filing 805 reports. The respondents said that the committee was also responsible for monitoring utilization, initial screening activities, 809 hearings, and submitting 821.5 reports.

The committees have oversight responsibility for physician practice quality and safety issues, such as gross or flagrant care issues, limitation of practice, practice patterns not consistent with standards of care, egregious events, repeated errors, multiple patient complaints, and multiple physician complaints. They also are frequently responsible for monitoring required proctoring, quality screening issues, employee complaints, health plan complaints, and utilization review and risk management issues (see Table 4.11).

Membership on peer review committees involves a certain time commitment, and we were interested in knowing how difficult it was to replace members on the committee. Based on our survey data, on average, one person declined to be on the peer review committee for every four that were asked (see Table 4.12). We also asked physicians why they agreed to serve on a peer review committee (see Table 4.13). Most indicated a willingness or interest in peer review; others had experience in peer review; or it was required by the entity (see Table 4.13).

Table 4.11: Online Survey - Peer Review Body Tasks
(214 eligible respondents; 123 actual respondents; percentages based on a denominator of 123)

Indicate responsibilities of the peer review body: (check all that apply)	n	%
Quality of care concern (evaluate)	112	91.1%
Series of complaints/events about physician	107	87.0%
Sentinel event	98	79.7%
Secondary or final determination of action, if any, to be taken for a patient care issue related to a physician's practice	97	78.9%
Tracking or monitoring of a physician's practice issue	92	74.8%
Utilization of care (evaluate)	87	70.7%
A physician's practice pattern	87	70.7%
Submit an 805 report	72	58.5%
Submit an 821.5 report	60	48.8%
Initial screening for patient care issue related to a physician's practice	59	48.0%
Convene or oversight of an 809 hearing	57	46.3%
Initial screening for patient care issue related to an entity or systems-problem	50	40.7%
Other	20	16.3%

Table 4.12: Online Survey - Peer Review Body Membership Changes
(214 eligible respondents)

In the last calendar year,	n	Mean	sd
How many new members were added to the peer review body?	128	3	5.7
How many individuals were approached to serve on a peer review body?	101	4.1	6.5
If applicable, of those approached, how many refused?	73	1.1	2.3
How many unanticipated member changes have occurred in the peer review body?	127	0.5	1.1

Table 4.13: Online Survey - Peer Review Body Reasons for Serving
(74 eligible responses; 64 actual respondents; percentages based on a denominator of 64)

Identify the reason(s) you agreed to serve on the Peer Review Body? (check all that apply)	n	%
Willingness to serve	52	81.3%
Interest in peer review	46	71.9%
Experience in peer review	29	45.3%
Requirement for affiliation/employment	9	14.1%
Other	7	10.9%
Payment is offered by entity	4	6.3%
Scheduled/rotating obligation	3	4.7%
Requirement for hospital privileges	2	3.1%

Depending on the entity, various individuals and committees are responsible for determining whether to refer an issue/event to a higher level review, including the committee chair or a majority of members of peer review committees, credentialing committees, department committees, professional affairs committees, and risk management committees.

Fifty-six percent of the respondents indicated that a majority vote of the initial committee was required to refer the issue to a higher-level review body within the entity, and 69.5% of the respondents reported that the committee chair made the decision (see Table 4.14). Fifty-six percent of respondents reported that the decision to forward an 805 report to the MBC was made by a majority of the final decision-making committee (see Table 4.11).

Table 4.14: Online Survey - Peer Review Body Referral Mechanisms
(214 eligible respondents; 118 actual responses; percentage based on denominator of 118)

Indicate the position of the person, committee, or mechanism that determines whether to refer an issue to a secondary or higher review body in the entity:	n	%
Peer review chair	82	69.5%
A majority vote of the initial screening committee	67	56.8%
Credentialing Committee decision	66	55.9%
Medical Department Chair	62	52.5%
Chair of initial screening committee	53	44.9%
Entity policies & procedures	48	40.7%
Risk Management Committee decision	33	28.0%
A majority vote of the Medical Department members	24	20.3%
Professional Affairs Committee decision	14	11.9%

Table 4.15: Online Survey - Peer Review Body Reporting Mechanism
(214 eligible respondents; 124 actual respondents; percentages based on a denominator of 124)

Indicate the person, committee, or mechanism that determines whether an issue (805 or 821.5) is reported to the Medical Board of California (MBC):	n	%
A majority vote of the final review committee	70	56.5%
Other	50	40.3%
Chair of secondary or final determination committee	25	20.2%
Entity policies & procedures	23	18.5%
Peer review chair	18	14.5%
Credentialing Committee decision	15	12.1%
Risk Management Committee decision	5	4.0%
Medical Department Chair	4	3.2%
A majority vote of the Medical Department members	4	3.2%
Professional Affairs Committee decision	3	2.4%

Most respondents (69%) knew that an 805 or 821.5 report must be submitted within 15 days of the event being reported (see Table 4.16), and 67% knew that a supplemental report was to be submitted within 30 days of the physician completing the terms of the discipline.

Fifty-six percent of the respondents knew that an 821.5 report was to be submitted to the MBC within 15 days of the initiation of a formal investigation and knew the timeframe within which the MBC diversion program administrator must contact the reporting peer review body (see Table 4.16).

Table 4.16: Online Survey - Reporting Time Frames

(214 eligible respondents; actual respondents are listed in "Total" row; percentages calculated using the actual respondents as the denominator)

	After a reportable event (805 or 821.5), the entity's designated peer review officer must submit a report to the relevant agency within how many days		After the licentiate has satisfied the terms of a disciplinary action, a supplemental report is made to the relevant agency within how many days:		After initiating a formal investigation of a potential 821.5 event, the entity's designated peer review officer must submit a report within how many days:		Upon receipt of an 821.5 report, the MBC diversion program administrator shall contact the reporting peer review body within how many days:	
	n	%	n	%	n	%	n	%
Correct	78	69.0%	76	67.3%	64	55.7%	70	63.6%
Not correct	35	31.0%	37	32.7%	51	44.3%	40	36.4%
Total	**113**	**100.0%**	**113**	**100.0%**	**115**	**100.0%**	**110**	**100.0%**

Most respondents knew some of the criteria for filing 805 or 821.5 reports (see Tables 4.17 and 4.18). However, the items listed in Tables 4.17 and 4.18 are all criteria for completing 805 or 821.5 reports so each respondent should have checked all of the items except "other." The respondents indicated various resources to use when they needed information with the most frequently cited source for information being the law or code itself (see Table 4.19).

Table 4.17: Online Survey - Peer Review Body Criteria for Filing 805 Reports
(350 eligible respondents; 212 actual respondents; percentages based on a denominator of 212)

Indicate the criteria used for filing an 805 report: (check all that apply)	n	%
When a peer review body takes an action that terminates or revokes a licentiate's membership, staff privileges, or employment	162	76.4%
When a peer review body imposes or a licentiate voluntarily accepts restrictions on staff privileges, membership, or employment for 30 days or more for any 12-month period, for medical disciplinary cause or reason	156	73.6%
When a peer review body denies or rejects a licentiate's application for a medical disciplinary cause or reason	140	66.0%
The imposition of summary suspension of staff privileges, membership, or employment, if the summary suspension remains in effect for a period in excess of 14 days	136	64.2%
After notice of either an impending investigation or the denial or rejection of the application for a membership, privilege, or employment for a medical disciplinary cause or reason	111	52.4%
Other	42	19.8%
Resignation or leave of absence, withdrawal or abandonment of a licentiate's application, or request for renewal of privileges or membership	39	18.4%

Table 4.18: Online Survey - Peer Review Body Criteria for Filing 821.5 Reports
(214 eligible respondents; 117 actual respondents; percentages based on a denominator of 117)

Indicate the criteria used for filing an 821.5 report for a physician or surgeon POSING A THREAT TO PATIENT CARE: (check all that apply)	n	%
Physician or surgeon suffering from a disabling mental condition	98	83.8%
Physician or surgeon suffering from a disabling physical condition	93	79.5%
Physician or surgeon suffering from a substance abuse condition	90	76.9%
Other	18	15.4%

Table 4.19: Online Survey - Peer Review Body Resources
(70 eligible respondents; 46 actual respondents; percentages based on a denominator of 46)

For either the 805/821.5 report, identify the resources available to assist you in your determination for filing:	n	%
Review of 805/821.5 legal codes	37	80.4%
Web sites	27	58.7%
Entity documents	27	58.7%
Discussions with licensing authorities	24	52.2%
Other	17	37.0%
None	1	2.2%

Summary of Requirement I
Based on the study results, a summary of the findings for Requirement I follows.

1. Variation exists across entities in how they define and conduct "peer review," including:
   - Events that trigger peer review.
   - Procedures that are followed after peer review.
   - Tracking of peer review issues.
   - Expertise of the non-physician support employees and the physician reviewers and chairs.

2. Peer review by entities in California involves common procedures or practices, including:
   - Using remediation for substandard physician care that may last for 12-24 months before taking an action requiring an 805 report.
   - Credentialing of a physician as the initial peer review interaction with peer review activities occurring between the periodic re-credentialing of physicians.
   - Routinely screening a certain percentage of patient records to check for evidence of substandard care.
   - Combining and discussing all types of risk management events and actions (not just activities involving physicians and medical staff) in "peer review" committees, as well as mundane issues related to running the business of the entity.
   - Initiating peer view with a non-physician support staff member performing an explicit review of a medical record.

3. The identification and timeframe for resolving peer review issues depends on a number of factors within each entity, including:
   - The severity of an event, as determined by the person who learns of the event and those persons who become involved in this process. (Our review of committee minutes demonstrated that the process is very lengthy, involving months or years of re-review, review of more records, interviews with the physician, remediation, and/or other investigation methods within the entity.)
   - The entities' own policies and procedures related to peer review.
   - Decision-making committees having multiple responsibilities, including managing overall quality of care issues and complaint/sentinel event investigation, monitoring physician practice and practice patterns, determining disciplinary action, filing 805 reports, conducting utilization, initial screening activities, and 809 hearings, submitting 821.5 reports, proctoring, employee complaints, and working with health plan complaints and risk management issues.

4. Survey respondents knew some, but not all, of the criteria for filing 805 and 821.5 reports and 809 hearings.

Requirement II: 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.

A substantial amount of anxiety about the study was exhibited by the entities, particularly hospitals. Thirty-seven (49 of 132) percent of hospitals communicated with us through attorneys, although only a few health plans or medical groups communicated using attorneys. A number of hospitals or attorneys sent letters (see Appendix III: Hospital Related Documents) detailing reasons for declining to submit certain documents. Most of the letters refer to laws and case law described in Table 2.2. Some hospitals also invited us to visit the facilities for more information.

Most of the letters also refer to a conference call held on October 5, 2007. This call was arranged by the California Hospital Association, ostensibly to allow Lumetra to answer questions posed by various hospitals. However, a few individuals dominated the call and expressed a desire to substantially change the study design.

We answered the questions as best as possible, referred the individuals to the legislation, and terminated the call after one hour. As a result of this meeting and other indications of general anxiety regarding the study, we set up a Web site that described the study purposes and the pertinent legislation, and posted answers to some frequently asked questions.

Since we also had been contacted by various individuals who wanted to influence the study design, we invited people who visited the Web site to e-mail comments to an e-mail box that could be accessed through the site. In order to maintain our independence from outside influence, we agreed to review the comments at the end of the study and include them in the final report (see Appendix IX: Comments About Study).

As indicated in the letters from entities (see Appendix III: Hospital Related Documents), fear of legal "discovery" of protected information was the main reason given for declining to send peer review minutes. The second most common reason given for declining to send minutes was the effort and personnel required to compile the minutes.

We discovered that most entities do not have the documents in electronic form, and many have them stored offsite. Most entities do not appear to have a readily accessible tracking system that allows the staff members to efficiently follow events over time. Additionally, during the study there were two entities that were purchased and the new owner claimed to have no access to minutes or other documents prior to the time when the purchase occurred.

A large share of entities submitted policies, procedures, and bylaws but declined to submit committee minutes (see Table 4.5). Even after lengthy reassurances and identification of the safeguards imposed in the 805 legislation, there were still 177 entities that refused to send minutes. The ability to review committee minutes was critical to determine whether entities were complying with the reporting requirements. Additionally, it was not sufficient to review only 805 reports because it was also necessary to review events and decision-making that did not trigger 805 reports.

Some entities created event summaries that detailed events leading to 805 reports or events that might lead to 805 reports. Because the histories of the events are important, and the histories occur over months or years, the summaries allowed us to track events more efficiently.

Since the study had time and cost constraints, the document review was our primary way to determine whether entities were in compliance with the law. Therefore, we decided to add a number of site visits to the study in order to review documents that the entities refused to submit. The site visits are discussed in the Study Validation Measures section of this chapter.

We reviewed minutes provided by 68 entities and additionally reviewed minutes during the site visits. We also had access to an entity's sample of events and histories for those entities that provided event summaries. Participant entities screened a large number of cases through the routine monitoring process (typically a set percentage of various diagnoses) and selection of cases. These selected cases are peer reviewed in the various committees generally using implicit peer review (i.e., using the reviewers' professional judgment). One large hospital claimed to have screened over 8,000 cases in the five years for which data were requested (see letters in Appendix III: Hospital Related Documents).

Based on the review of committee minutes and cases and discussions with participants, we estimate that a small percentage of routinely screened cases are forwarded to the medical executive/decision making committee for further review, and a still smaller percentage of those cases forwarded results in an action that limits or terminates a physician's privileges for medical cause or reason, thus triggering an 805 report to the Medical Board (see Table 2.4). We were unable to determine an exact percentage for the following reasons:

1. The tracking of cases over time in most entities is poor or lacking.
2. One of the first actions by an initial peer review committee (such as a department committee) is to ask the subject physician to come to the next meeting to discuss the event or for the chair of the committee to speak with the subject physician to understand the subject physician’s thinking about the event.
3. Often the subject physician is delayed or the chair is delayed and the matter is held until the following month's agenda or a later agenda.
4. The event or case was not documented in future minutes to which we had access or because the discussion between the physician and the chair happened away from the committee meeting.
5. Following events through minutes of other committees was difficult or impossible because there might not have been any record in the minutes of a follow-up meeting or the follow-up meeting occurred months after the initial event.
6. The committee minutes include issues other than peer review activities, and in some entities, comments about follow-up cases are often missing or limited.

Because there are proportionally few sentinel events, major employee or physician complaints, or events that are particularly egregious or unexpected per number of patients and related to physician practice, these events are almost always forwarded to a higher-level review committee (see Figure 4.2).

Based on our review, we observed that overall the entities are following the letter of the law regarding 805 reporting. Using minutes and event summaries, we discovered that entities try numerous remedial interventions (peer counseling, education, training, mentoring, observation, behavior counseling, UCSD Physician Assessment and Clinical Education (PACE) Program[32]) before informing the physician that a "final proposed action" is being taken. The process to this point is almost never

shorter than one year. Also adding to the process is the disagreement about how to interpret two parts of the California codes: 805 (c) and 809.2 (h).

Business and Professions Code Section 805 (c) states that an 805 report will be filed "within 15 days after any of the following occur after notice of either an impending investigation or the denial or rejection of the application for a medical disciplinary cause or reason" (see Table 2.4)[1]. However, Business and Professions Code Section 809.2 (h) states, "A hearing under this section shall be commenced within 60 days after receipt of the request for hearing, and the peer review process shall be completed within a reasonable time, after a licentiate receives notice of a final proposed action or an immediate suspension or restriction of clinical privileges (underline added), unless the arbitrator or presiding officer issues a written decision finding that the licentiate failed to comply with subdivisions (d) and (e) in a timely manner, or consented to the delay" (see Table 2.3)[1].

Based on focus group and key informant interview data, we learned that some attorneys advise their client entities to behave in the most conservative manner to ensure physician rights. Thus, these entities do not file any 805 reports until after an 809 hearing when the physician (licentiate) receives notice of a "final proposed action." Other attorneys reported that they interpret the code to mean that the 805 is filed after an 809 hearing, unless there is a summary suspension or immediate termination. Therefore, in those entities, 805 reports would not be filed unless there was a summary suspension of more than 14 days or an immediate termination.

Key informants reported that the 809 hearing for due process can add 2-5 years to the process of filing an 805 report. Several affected physicians reported taking various legal actions that further delay the 805 reporting. Some attorneys expressed that they believed they are guilty of legal malpractice if they do not delay the 805 reports as long as possible for their client.

Although there is disagreement about the potential threat to a career, physicians who have been the subject of an 805 report state that it is difficult or impossible to find a new position, their professional lives are ruined, other entities will not grant privileges even if they have fulfilled the terms of the discipline, and they spend years and hundreds of thousands of dollars in court trying to clear their professional names and reputations.

Based on reviews of the minutes from participant entities and key informant interviews, the most common reasons for cases being referred for peer review to a high level (executive medical staff) committee are 1) disruptive physician behavior/impairment (821.5), 2) substandard technical skills, and 3) failure to document/record patient treatment.

Impairment cases have frequently been referred to the diversion program through the MBC. However, this program was terminated effective June 30, 2008. MBC staff members reported that in the diversion program, records of events are required to be destroyed as soon as the case is closed, so there is no means to track recidivism of drug or alcohol use.

Mental or physical illness that impairs a physician's ability to practice medicine safely is also a reason for changes in privileges that require 821.5 or 805 reporting. Bylaws, policies and procedures indicate that physicians may be referred to the entity's "well-being" committee or other behavior modification committees or programs in order to remediate the substance abuse, anger outbursts, and/or mental or physical health issues that affect physician behavior. Because changing physician privileges triggers an 805 report, while the entity is trying to deal with this impaired or disruptive physician, the physician is allowed to continue to practice.

Minutes and event summaries from some entities indicate that physicians are allowed to commit multiple disruptive actions over many years while various strategies are tried or before any remediation is required. In one instance, a physician attended the PACE program but re-offended with the same disruptive behavior in the following year. All of this may occur before an 821.5 report is filed. It is also not possible to discover whether 821.5 reports are filed appropriately because of the codes protecting the rights of the physician.

Physicians having (or who develop) substandard technical skills can be trained, mentored, proctored, and assisted without triggering an 805 report as long as the training is not for medical cause or reason and there is no change in privileges (see Table 2.4). Minutes indicate that entities attempt these interventions to solve the problem before the behavior results in an event that triggers a reporting requirement.

Another common reason for referral to peer review or 805 reporting is for the physician who does not document medical care in a patient record. The lack of documenting eventually becomes so egregious that the entity is at risk for censure by licensing and accreditation agencies, so the entity withdraws or restricts the offenders' privileges and files an 805 report with the MBC.

During the study, key informants from participant entities suggested the elimination of failure to document as a reason for reporting to the Board because it appears to be a squabble between an entity and a physician who will not keep up on charting. However, if professionals agree that documentation of medical care is required to ensure a safe and quality environment in which to treat patients, then the requirement is no different than any other substandard medical practice.

Requirement II Summary

In summary, collecting the data to address Requirement II was a challenge because many of the entities, especially hospitals, expressed anxiety and concern in providing documents for review, particularly peer review minutes for fear of legal “discovery.” A second concern was the amount of effort, both in time and personnel, to compile these documents, since most entities do not maintain electronic records or store them offsite.

Our finding revealed the following about peer review and 805 reporting.

1. Event tracking capability of entities is limited due to:
    - Lack of a readily available tracking system that allows the staff members to efficiently follow events over time.
    - Lack of access to prior minutes or other documents by new owners when an entity is purchased.

2. Overall, entities follow the letter of the law regarding 805 reporting and screen a large number of cases through routine monitoring, but few cases lead to actual 805 filings, because of the following:
    - Disagreement/or legal interpretation about whether an 809 hearing is required before every 805 report is submitted.
    - 809 hearings for due process adding years to the process and delaying the filing of an 805 report.

3. Entities use other measures to correct physician behavior before resorting to filing an 805 report (which allows physicians to continue to practice and possibly commit multiple actions over many years before any steps are taken), including:

- Remedial interventions (e.g., peer counseling, education, training, mentoring, observation, behavior counseling, PACE Program).
- Referral to the Diversion Program (which is closing) for impairment cases.
- Bylaws, policies, and procedures that allow physicians to be referred to the entity's "well-being" committee or other behavior medication committee/program to remediate the causes affecting the physician behavior.

4. The most common reasons for cases being referred for peer review to a high level (executive medical staff) committee are 1) disruptive physician behavior/impairment (821.5), 2) substandard technical skills, and 3) failure to document/record patient treatment.

5. Most responses indicated people knew that mental or physical illness that impairs a physician's ability to practice medicine safely is also a reason for changes in privileges that require 821.5 or 805 reporting.

6. It is possible that some physicians would never be subject to peer review because they have practices that do not fit any peer review requirements.

Requirement III: A description and evaluation of the roles and performance of various State agencies, including the State Department of Health Services and occupational licensing agencies that regulate healing arts professionals, in receiving, reviewing, investigating, and disclosing peer review actions, and in sanctioning peer review bodies for failure to comply with Section 805.

In earlier chapters, we listed various State agencies, codes, and regulations that govern the entities in the study (see Table 1.1, 2.2; 2.7). The Department of Managed Care provides governance for HMOs and health plans; Title 22 and OSHPD have some governing responsibility for acute care hospitals. The Office of the Patient Advocate and OSHPD have some control over medical clinics. However, because of the limited timeframe, the focus of this study is on the Medical Board and the regulation of the practice of medicine in California.

In key informant interviews, we found that over the years other professional disciplines have developed State boards of control, so that the MBC only investigates physicians and podiatrists. The discipline-specific boards promulgate regulations governing the practice of individuals who are licensed or certified by the State. We found no systematic communication among these various boards and agencies that would coordinate patient quality and safety issues.

In order to fairly assess the role of the MBC, we reference the standards put forth by the Federation of State Medical Boards (FSMB) of the United States, Inc., which were developed by The Special Committee on Evaluation of Quality of Care and Maintenance of Competence, and approved by the Federation House of Delegates in April 1999[30]. Although some of the standards are beyond the scope of this report, we used quantitative data provided by the MBC and data from structured interviews with MBC staff members to respond to those that are relevant.

FSMB Standard One: State medical boards should develop and implement methods to identify physicians who fail to provide quality care and therefore warrant further evaluation by the State medical board.

This study details the activities that occur within entities prior to and following reporting to the Medical Board of California. The MBC has an extensive procedure to identify physicians who fail to provide quality care. Additionally, the MBC posts numerous public education messages and information on its Web site, which also includes reporting forms for different individuals and entities that are responsible for reporting to the MBC (see Appendix VII: Medical Board of California Documents).

The MBC has 400+ employees in 11 district/field and three probation offices located around the State performing numerous activities in addition to managing the work related to 805 reporting. The efforts to ensure quality are essentially complaint driven, although healthcare entities do provide routine quality screening.

The Board receives over 8,000 complaints (including 805 and all other complaints) annually, which are investigated by physicians and as necessary, MBC staff members with training as law enforcement officers, degrees in criminal justice, or detective-level experience in a police agency. The complaint review process (including 805 reports) is diagramed in Figure 4.4, the enforcement process in Figure 4.5, and the public disclosure process in Figure 4.6.

The diagrams demonstrate the multiple sources of complaints, the multiple ways different complaints are reviewed, and the complex outcomes of the complaints review that would initiate the enforcement process. The Board reviews all complaints to determine whether the complaint falls within the Board's jurisdiction and contacts the physician for a response. After receiving relevant information, the complaint is forwarded to a physician consultant for review of alleged specific standard of care violations. If there is no departure from the standard, the complaint is closed. If the complaint warrants further review, the physician forwards the complaint to one of the field offices for further investigation. In either case, both physician and complainant are notified of the complaint disposition.

The diagrams also illustrate the complexity of the complaint process, the enforcement process and the public disclosure rules. Public disclosure is limited by numerous codes and varies in whether entities or individuals have access to the information, how long a record stays on the Web site and how a request must be made.

An example of a lawsuit that impacted the disclosure laws is the 1993 suit filed by the California Medical Association (CMA) against the MBC to stop public disclosure of an MBC request of the Attorney General's office to file an accusation against a physician [116, 117]. This ruling protected the interest of the physician, but added to the complexity of the laws governing public disclosure. All of the processes are complex and multi-layered.

During the focus group interviews, some participants stated that the MBC did not appear to investigate all 805 reports, or if reports were investigated, the MBC often did not find any wrongdoing. Other participants stated that the MBC follow-up for 805 reports took frequently as long as a year after the report was submitted. Later in the chapter, we report the actual amount of time the MBC takes to investigate complaints. Based on these comments and actual times, it is not clear whether the Board follow-up is timely, and if not, what factors provide barriers to a more effective and efficient process.

Figure 4.4: The Medical Board of California Complaint Review Process

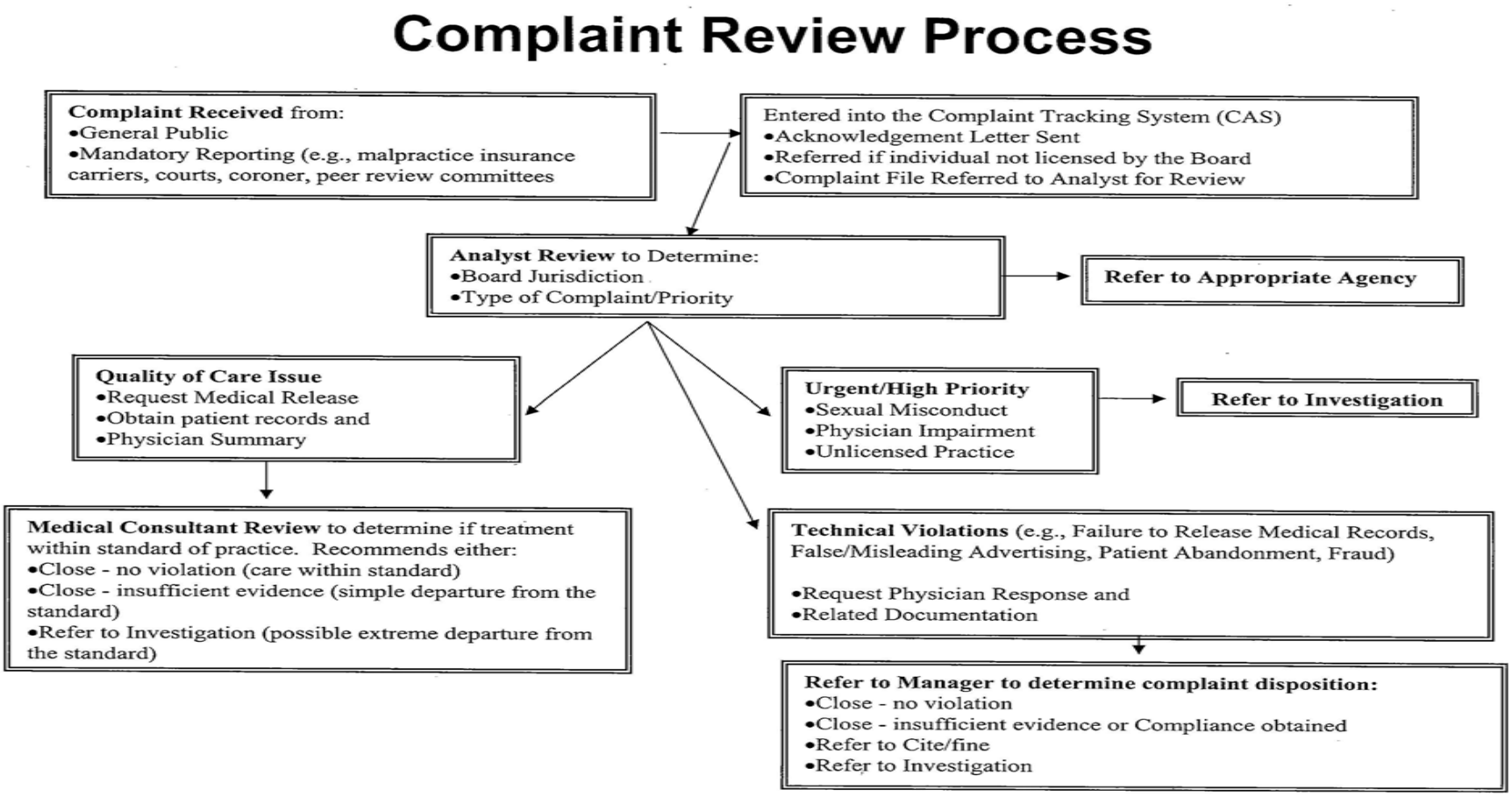


Figure 4.5: The Medical Board of California Enforcement Process

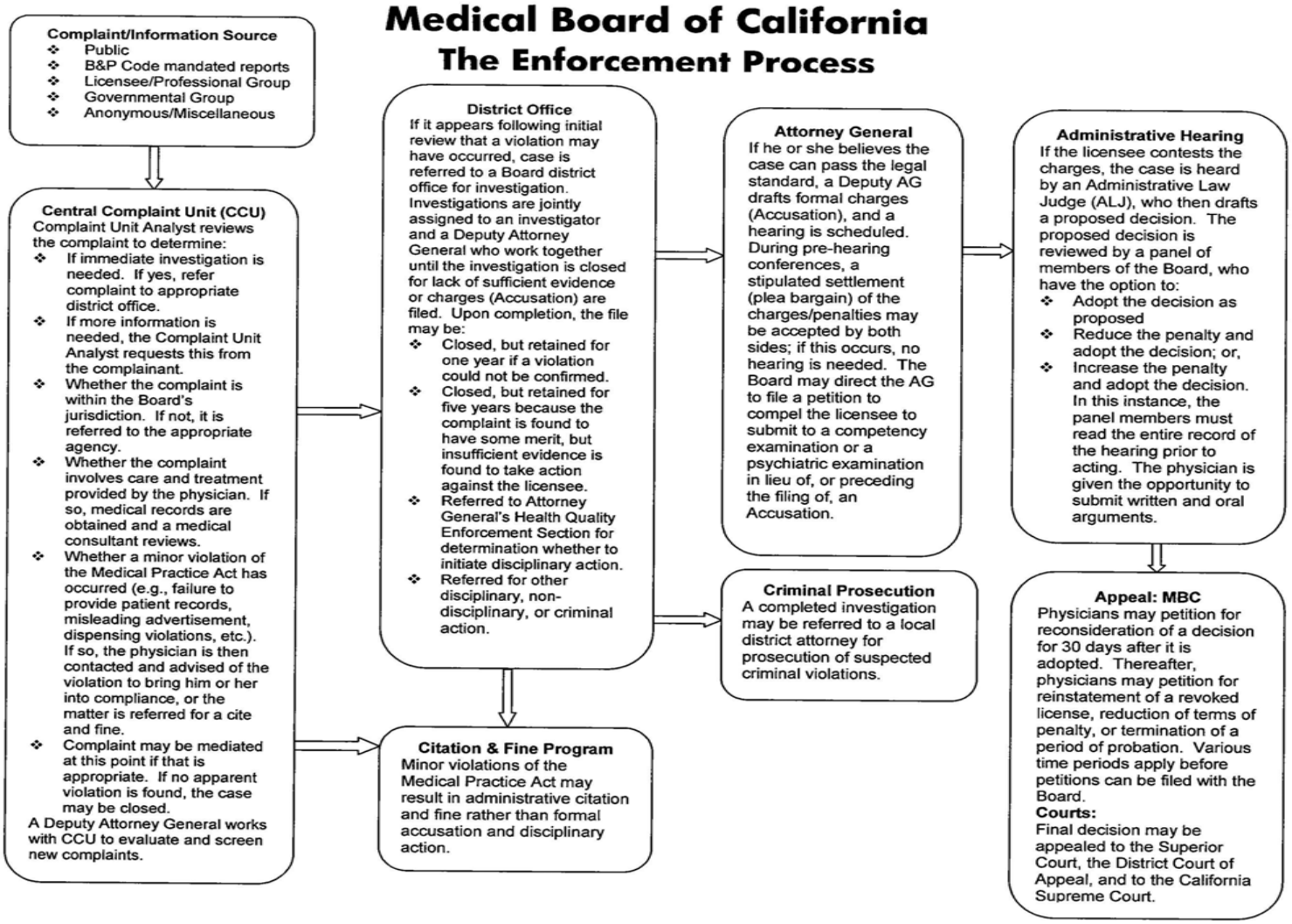


Figure 4.6: The Medical Board of California Public Disclosure Information

MEDICAL BOARD OF CALIFORNIA
PUBLIC DISCLOSURE INFORMATION
Revised January 1, 2007

CAS = Consumer Affairs System; PC = Penal Code; B&P = California Business and Professions Code; CCR = California Code of Regulations; GC = Government Code

		How Long the Document is available to Public	
Document	**When the Document is Made Public**	**Written Request/Walk-In Request**	**Web site/Phone Request**
PENAL CODE (PC) 23 SUSPENSION (Partial or full license restrictions per this code; limited or no practice allowed while suspension is in place)	Date issued by a criminal court	Available indefinitely	Pursuant to B&P 2027, available on physician's profile only during period when physician's license is suspended; deleted from profile/CAS* if suspension is lifted or if an administrative decision becomes effective. Available via Enforcement Public Document Search on the Web site unless suspension has been lifted by the Board.
AUTOMATIC SUSPENSION ORDER (B&P 2236.1) (Licensed suspended per this section; no practice allowed while license is suspended)	Date issued by Medical Board	Available indefinitely	Pursuant to B&P 2027, available on physician's profile only during period when physician's license is suspended; deleted from profile/CAS* if suspension is lifted or if an administrative decision becomes effective. Available via Enforcement Public Document Search on the Web site unless suspension has been lifted by the Board.
INTERIM SUSPENSION ORDER (ISO) (Licensee's practice has been temporarily restricted or suspended by an Administrative Law Judge, ALJ)	Date issued by an ALJ	Available indefinitely	Pursuant to B&P 2027, available on physician's profile only during period when physician's license is suspended; deleted from profile/CAS* if suspension is lifted or if an administrative decision becomes effective. Available via Enforcement Public Document Search on the Web site unless suspension has been lifted by the Board.

Page 1

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		How Long the Document is available to Public	
Document	**When the Document is Made Public**	**Written Request/Walk-In Request**	**Web site/Phone Request**
OUT-OF-STATE AUTOMATIC SUSPENSION ORDER (B&P 2310) (Licensee's practice in California is automatically suspended per notification of suspension or revocation of license in another state)	Date issued by Medical Board	Available indefinitely	Pursuant to B&P 2027, available on physician's profile only during period when physician's license is suspended; deleted from profile/CAS* if suspension is lifted or if an administrative decision becomes effective. Available via Enforcement Public Document Search on the Web site unless suspension has been lifted by the Board.
TEMPORARY RESTRAINING ORDER (TRO) (B&P 125.7) (Licensee's practice has been temporarily restricted or suspended by a court judge)	Date issued by a court judge	Available indefinitely	Pursuant to B&P 2027, available on physician's profile only during period when physician's license is suspended; deleted from profile/CAS* if suspension is lifted or if an administrative decision becomes effective. Available via Enforcement Public Document Search on the Web site unless suspension has been lifted by the Board.
ACCUSATION/PETITION TO REVOKE PROBATION/ACCUSATION AND PETITION TO REVOKE PROBATION (includes any amendments or supplementals)	Date filed by the Medical Board	Available indefinitely; or if withdrawn, available for one year from withdrawal date pursuant to Title 16 CCR Section 1354.5(b)	Available only prior to administrative decision becoming effective; once decision becomes effective, the posting of an Accusation is deleted and the outcome of the decision is posted; if the outcome of the decision is that the document is withdrawn or dismissed, the matter is completely deleted from the Web site pursuant to B&P 2027(a)(4)
STATEMENT OF ISSUES (Document, similar to an accusation, that lists reasons for denial of an application for licensure)	Date filed by the Medical Board	Available indefinitely	This information is not posted on a physician profile; the Statement of Issues is available via Enforcement Public Document Search on the Web site. If the outcome is to issue the license and place it on probation, that outcome is posted to the physician profile on the Web site

		How Long the Document is available to Public	
Document	**When the Document is Made Public**	**Written Request/Walk-In Request**	**Web site/Phone Request**
DISMISSED ACCUSATION (Accusation dismissed after administrative hearing)	Date filed by the Medical Board	Available indefinitely pursuant to GC 11517	Deleted from Web site/CAS pursuant to B&P 2027(a)(4)
CITATION ORDER (Citation is a written order describing the nature of a violation, including the specific code of law violated; it is not a disciplinary action)	Date issued by the Medical Board	Available for 5 years from decision date; if withdrawn or dismissed, it is purged immediately pursuant to Title 16 CCR Section 1364.15	Available for 5 years from decision date, or if withdrawn or dismissed, deleted immediately from Web site/CAS pursuant to Title 16 CCR Section 1364.15
PROBATIONARY CERTIFICATE (Conditional license issued to an applicant on probationary terms and conditions)	On the ordered date, after adoption by Division of Licensing	Available indefinitely	Available for the duration of probation.
PUBLIC LETTER OF REPRIMAND (B&P 2233) [A lesser form of discipline that can be negotiated for minor violations before the filing of formal charges (accusations)]	Date issued by the Medical Board	Available indefinitely	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the effective date of the decision

Document	When the Document is Made Public	How Long the Document is available to Public	
		Written Request/Walk-In Request	Web site/Phone Request
STIPULATED DECISION = A form of plea bargaining; the case is negotiated and settled prior to trial DEFAULT DECISION = A Decision which is rendered after the physician refuses or fails to participate in the disciplining process			
• Surrender (While charges are pending, licensee surrenders the license)	On the ordered date, after adoption by Medical Board	Available indefinitely	Available indefinitely
• Revocation, suspension, probation, limitation on practice (e.g. placed in disabled, inactive, or retirement status, etc)	On the ordered date, after adoption by Medical Board	Available indefinitely	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the effective date of the decision
• Public Reprimand/Public Letter of Reprimand (whether or not the Accusation is withdrawn)	On the ordered date, after adoption by Medical Board	Available indefinitely	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the effective date of the decision
• Education course, examination, and/or cost recovery reimbursement (whether or not the Accusation is withdrawn)	On the ordered date, after adoption by Medical Board	Available indefinitely.	Not available pursuant to B&P 2227(b)
• Citation Issued with terms and conditions: an education course, examination and/or cost recovery (whether or not the Accusation is withdrawn)	On the ordered date, after adoption by Medical Board	Available five years from decision date pursuant to Title 16 CCR Section 1364.15. (Only citation document available)	Available five years from decision date pursuant to Title 16 CCR Section 1364.15
• Accusation Withdrawn (Accusation filed by AG's Office was withdrawn before administrative hearing)	Date document filed by Medical Board	Available for one year after withdrawal date pursuant to Title 16 CCR Section 1354.5(b)	Not available pursuant to B&P 2027(a)(4)

Document	When the Document is Made Public	How Long the Document is available to Public	
		Written Request/Walk-In Request	Web site/Phone Request
DECISIONS AFTER AN ADMINISTRATIVE PROCEDURES ACT HEARING			
• Revocation, suspension, probation, limitation on practice (e.g. placed in disabled, inactive, or retirement status, etc)	30 days after receipt by Medical Board or upon adoption, whichever occurs first	Available indefinitely	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the effective date of the decision
• Public Reprimand/Public Letter of Reprimand (whether or not the Accusation is withdrawn)	30 days after receipt by Medical Board or upon adoption, whichever occurs first	Available indefinitely	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the effective date of the decision
• Education course, examination, and/or cost recovery reimbursement (whether or not the Accusation is withdrawn)	30 days after receipt by Medical Board or upon adoption, whichever occurs first	Available indefinitely	Not available pursuant to B&P 2227(b)
• Accusation Dismissed (Accusation has been dismissed after administrative hearing)	30 days after receipt by Medical Board or upon adoption, whichever occurs first	Available indefinitely	Not available pursuant to B&P 2027(a)(4)
SURRENDER of LICENSE DURING PROBATION (w/o further administrative action pending)	Date issued by Medical Board	Available indefinitely	Available indefinitely
JUDGMENT/ARBITRATION AWARD (only the information regarding the matter is available, no documents are available from the Medical Board)	Date Medical Board notified or made aware	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the date the Medical Board obtains the information ****	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the date the Medical Board obtains the information
MEDICAL MALPRACTICE SETTLEMENTS (only the information regarding the matter is available, no documents are available from the Medical Board)	When the Medical Board is notified that a licensee has three (low-risk category) or four (high-risk category) settlements within a 10 year period pursuant to 803.1(b)(2)	The information is public during each 10 year period that the licensee has three or four settlements; see B&P 803.1(b)(2)	Pursuant to B&P Code 2027(b)(1), the information is public during each 10 year period that the licensee has three or four settlements; see B&P 803.1(b)(2)

		How Long the Document is available to Public	
Document	**When Public**	**Written Request/Walk-In Request**	**Web site/Phone Request**
FELONY CONVICTION (only the information regarding the conviction is available, no documents are available from the Board)	Date Medical Board notified or made aware	Available indefinitely pursuant to B&P 2027(b)(2)	Available indefinitely pursuant to B&P 2027(b)(2)
MISDEMEANOR CONVICTION (only the information regarding the conviction is available, no documents are available from the Board)	Date Medical Board files an accusation related to the misdemeanor conviction.	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the date the Medical Board obtains the information ****	Pursuant to B&P 2027(b)(1), available for 10 years from January 1, 2003; or after January 1, 2003, for 10 years from the date the Medical Board obtains the information
**805 REPORTS to the public - resulting from termination or revocation of hospital privileges for medical disciplinary cause or reason (only the information regarding the termination/revocation is available, no documents are available from the Board unless requestor is another hospital or HMO pursuant to B&P 805.5 - see below)	Date Medical Board notified or made aware	Indefinitely, unless the privileges are restored; if privileges are restored it is public for 10 years from the restoration date pursuant to B&P 2027(b)(2)****	Indefinitely, unless the privileges are restored; if privileges are restored it is public for 10 years from the restoration date pursuant to B&P 2027(b)(2)
805 REPORTS given to ***authorized requesters pursuant to B&P 805.5 Authorized requesters may receive a copy of any 805 report (denial, removal, or restriction of staff privileges) except for the following: • reports for failure to complete medical records • reports found to be without merit by the Board	Date Medical Board notified or made aware	The information regarding a termination or revocation of hospital privileges is available indefinitely, unless the privileges are restored; if privileges are restored it is public for 10 years from the restoration date pursuant to B&P 2027(b)(2)**** The actual report is only available for 3 years from the date the Board received the report pursuant to 805.5(b)(3)	The information regarding a termination or revocation of hospital privileges is available indefinitely, unless the privileges are restored; if privileges are restored it is public for 10 years from the restoration date pursuant to B&P 2027(b)(2) Information regarding the number of 805 reports for a licensee is posted on the "authorized requestor" Web site for 3 years pursuant to 805.5(b)(3) with the same exceptions as listed under the Document section

* CAS or the Consumer Affairs System, is the database used by the Medical Board to track licensing and enforcement activities.
** 805 Report is a facility initiated discipline report on a physician provided by a hospital, clinic, medical group or clinic, HMO, etc., pursuant to B&P 805.
*** Authorized requestor could be an HMO, hospital, physician requesting for him, or his attorney requesting with written permission from the physician, etc.
**** The law does not require the Board to delete this information from its files, only that the information is no longer displayed on the Board's Web site.

FSMB Standard Two: States should enact mandatory reporting requirements and state medical failing to comply with reporting requirements. The disciplinary function of all state medical boards is boards should be provided the authority to impose penalties upon those individuals and institutions primarily complaint driven. Therefore, a board's effectiveness in handling quality of care cases is enhanced by its ability to receive valid information from reliable sources.

California has multiple codes and laws describing mandatory reporting requirements (see Appendix VII: Medical Board of California Documents) and the Board has the ability to impose penalties ($10,000 fines) on those entities and individuals that fail to comply. During the site visits to the MBC and the review of data and documents that were provided, it was clear that the MBC has internal policies and procedures for initiating "failure to file 805 reports" investigations, as well as how 805 reports are handled within the agency. The MBC staff report that 805 reports are considered urgent complaints and are given top priority within the Central Complaint Unit of the Board.

The MBC staff members reported filing several actions between 2003 and 2008 against entities and individuals for failing to file an 805 report. These actions included five administrative actions against physicians; three active investigations are in process and eight have been closed against physicians or entities; six complaints have been closed; and four civil actions have been filed. Because the Board is dependent on an external source, such as a complaint from the public, to trigger an investigation into an event that should have resulted in an 805, it may be that the Board is not aware of all potential cases of failure to file 805s.

Based on the various interpretations of the 805 and 809 laws by attorneys mentioned earlier in the chapter, it is also not clear that the Board receives valid and complete information from entities or individuals when investigating 805 reports, even with subpoena power. Information provided in the 805 documents is minimal and frequently does not provide the history of events that have occurred prior to the 805 report. It is likewise not evident that the Board receives information in a timely manner, given the interpretation of legislation relating to allowing an 809 hearing prior to filing an 805 report.

Although there is a common perception that all the information about complaints is public information, the Board has multiple restrictions governing the posting of information on the Web site about physician behavior. Although entities can obtain more detailed information, it is often difficult for the general public to obtain the history of a particular physician. The MBC Web site provides frequently asked questions about public information and disclosure and also what is available on the physician license lookup site (see Appendix VII: Medical Board of California Documents). Figure 4.6 summarizes what the MBC can legally disclose, to whom it can be disclosed, and how long the information is allowed to remain on the physician profile Web site.

We were able to investigate in more detail the 805 reports received by the MBC in 2007. In fiscal year 2007, the reports came from 109 different entities involving 144 physicians in 171 events. Twenty-five physicians had multiple 805 reports in 2007. Based on data provided by the MBC about entities, we found that 98% of the entities that filed an 805 did so in less than a year after taking an action against a physician. In slightly more than 1% of the cases, the entities took longer than a year to file an 805 after they had taken an action.

MBC staff members raised the concern that in some instances an entity files an 805 report **after** the MBC takes an action. We investigated this and discovered that in fiscal 2007 there were seven

instances where the MBC hot sheet report specified an action taken by the MBC and the entity filed an 805 report after the hot sheet was circulated.

Table 4.20 displays the reasons for 805 reporting. Note that imposition of summary suspension for longer than 14 days and termination or revocation of privileges for medical cause or reason are the categories that require public reporting on the physicians' Web profile. Therefore, many of the 805s are not available to the public, although some are available to authorized requestors.

Table 4.20: Reasons for 805 Reports in California – 2007

805 Report Description	n	%
Imposition of summary suspension on staff privileges	37	21.6%
Licentiate resigned from staff	18	10.5%
Other - Review Comments	18	10.5%
Restriction(s) imposed on staff privileges	17	9.9%
Restriction(s) voluntarily accepted on staff privileges	12	7.0%
Termination or revocation of membership	11	6.4%
Licentiate resigned from employment	9	5.3%
Licentiate took leave of absence from staff	9	5.3%
Termination or revocation of staff privileges	9	5.3%
Termination or revocation of employment	8	4.7%
Denial/rejection of application for membership	6	3.5%
Licentiate resigned from membership	5	2.9%
Imposition of summary suspension on employment	3	1.8%
Denial/rejection of application for staff privileges	2	1.2%
Imposition of summary suspension on membership	2	1.2%
Restriction(s) imposed on membership	2	1.2%
Licentiate took leave of absence from membership	1	0.6%
Restriction(s) imposed on employment	1	0.6%
Restriction(s) voluntarily accepted on employment	1	0.6%
Total	171	100.0%

Over 43% of the physicians who were the subject of a report had information on the MBC public web profile; conversely, 56% percent did not. So, if a member of the public looked up one of the 78 physicians who were not on the Web site, they would have no reason to suspect that there had been an event that had triggered an 805 report. Of the 60 physicians found on the MBC public Web site nearly one-half of the events had occurred prior to 2007 (see Table 4.21). This indicates that the 805 reports were not posted on the public site until several months after the event. However, if the public date was prior to 2007, the report may represent a different event than the 805 reported in 2007. In any case, only 33 of 138 physicians with 805 reports could be found in the public Web site stemming from their most recent event.

Table 4.21: Public Reporting of 805 Reports in California – 2007

	n	%
Physicians on Public Web site	60	43.5%
Physicians not on Public Web site	78	56.5%
Total Physicians Reported	138	100.0%
	n	%
Public Dates Prior to calendar year 2007	27	45.0%
Public Dates calendar year 2007 or Later	33	55.0%
Total Physicians on Public Web site	**60**	**100.0%**

FSMB Standard Three: State medical boards should develop and implement proactive methods of identifying the individual dyscompetent physician, as well as opportunities for improving physician practice in problematic areas.

The MBC's function is primarily reactive rather than proactive. Although it may be possible to increase the proactive methods, it is not clear whether an agency charged with investigation and disciplinary action is the appropriate agency to proactively identify and remediate dyscompetent/incompetent physicians.

A dyscompetent physician is defined as one who requires retraining or updated training. As mentioned previously, the agency has numerous public information documents on the Web site (in both English and Spanish) to assist the public in understanding the rights and responsibilities of the MBC. There are also many documents that inform physicians about their rights and responsibilities.

The primary concern of the MBC is patient safety and protection. Changing or adding to the perspective of the Board from reactive to proactive would take a specific culture shift, particularly since the current system is deeply grounded in the legal system and uses punitive measures to discipline physicians.

FSMB Standard Four: State medical boards should implement and utilize processes to enhance evaluation and investigation of cases wherein the quality of care rendered is in question.

The MBC has extensive investigation teams throughout the State. Several focus group participants complained that the investigation process was very slow, so we traced through the system a specific event related to a complaint. A hospital submitted two 805s to the MBC, one in December 2006 and the second in March 2007.

The 805 reporting form indicated the reason for the first report was a restriction in privileges and the reason for the second was that the physician resigned from the entity. The supporting documentation submitted with the reports indicated that the physician had first been summarily suspended and then terminated, neither of which was indicated on the reporting form.

When we followed up with questions to the parties about that specific 805, the summary suspension had been for less than 14 days so it was not listed as the reason for the 805 report and the termination/resignation was reported as a resignation. Therefore, the MBC counted the disciplinary actions as restriction and resignation, as reported on the form. The event ultimately raised two issues:

1. Since the 805 was not reported as a summary suspension and termination, the 805 could not be made available to the public, so future patients had no way of knowing the history of this physician. Why did the entity only report the disciplinary action as restriction and resignation? The suspension was for fewer than 14 days and the physician was allowed to "resign."
2. The entity reported that the MBC did not request the patient record for at least six months after the last 805 was filed and has not presently (May 2008) issued a ruling from the investigation.

We investigated whether the forms used by the MBC to report an 805 event were easy to use. The respondents did not find them difficult, so that is not likely a reason for not reporting (see Table 4.22).

Table 4.22: Online Survey - Peer Review Reporting Forms Difficulty
(214 eligible respondents)

	n	Mean	sd
What is the level of difficulty (e.g. user-friendliness, clear documentation) for using the MBC's current 805 reporting forms? (1 = Not Difficult - 5 = Very difficult)	124	2	1

FSMB Standard Five: State medical boards should utilize a list of qualified physicians from which to select peer review panels in the evaluation and investigation of quality of care cases.

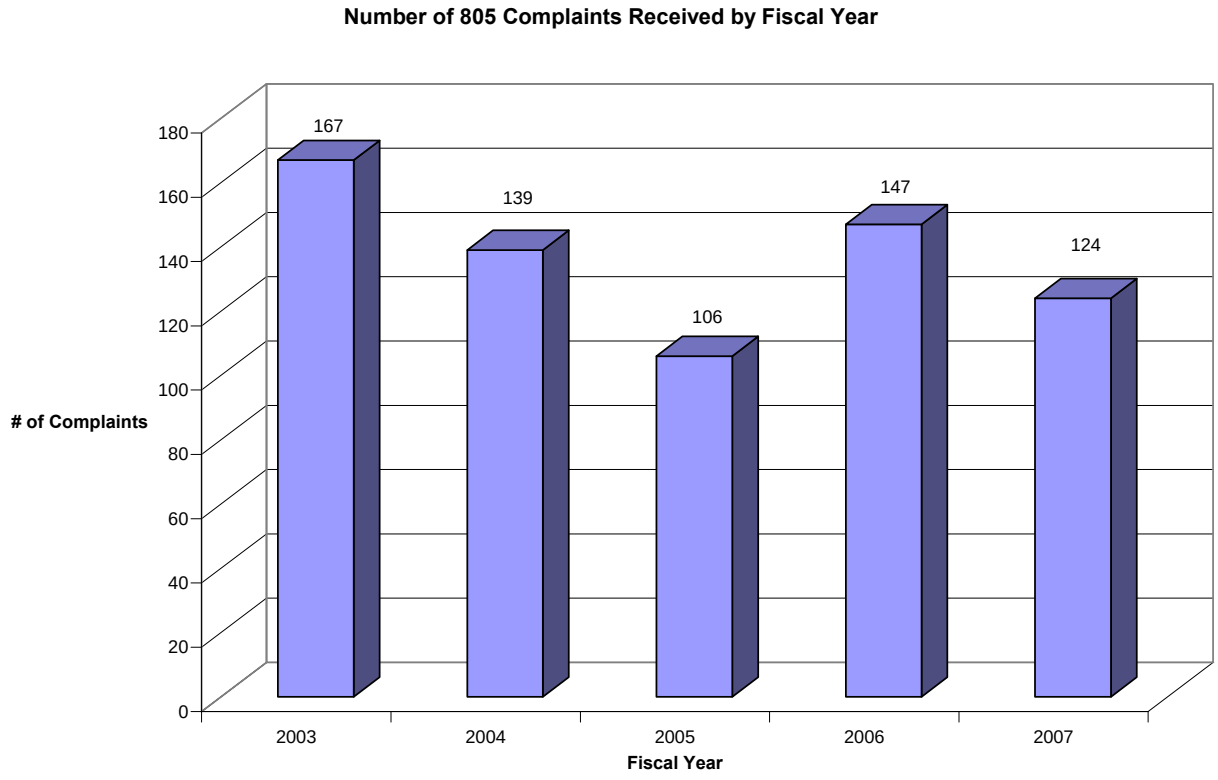
The MBC has policies and procedures in place that provide for the employment of qualified reviewers. The MBC 2006-07 annual report indicates an 11.6% vacancy rate of investigative staff

and that recruitment and retention are a continuing problem. Investigators are able to find employment with higher compensation at agencies where the work is less difficult[118].

FSMB Standard Six: State medical boards should develop and implement systems to efficiently process quality of care complaints processed in a timely and efficient manner.

As mentioned previously, in focus groups and key informant interviews, the MBC has been criticized for failing to investigate all 805 reports and failing to respond to complaints (805s) in a timely manner. Figure 4.7 illustrates the number of 805 reports received by the MBC over a five-year period.

Figure 4.7: Number of 805 Complaints Received by the MBC by Fiscal Year

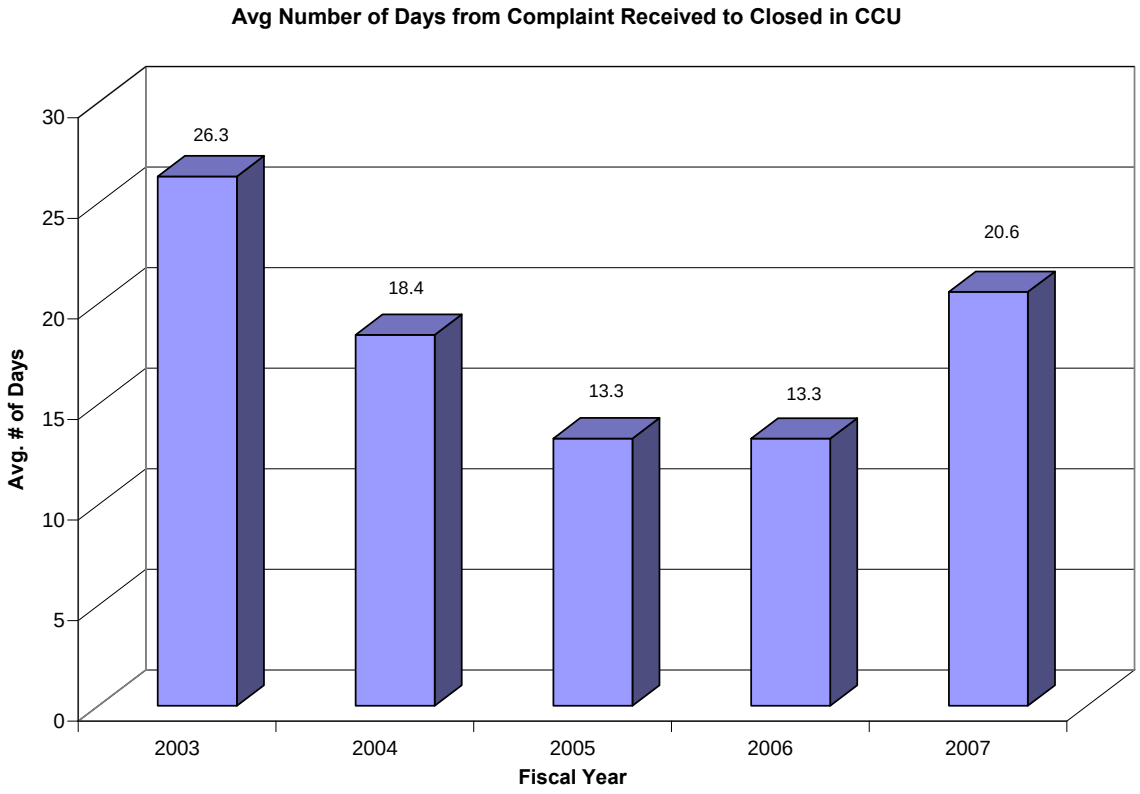


When the Central Complaint Unit (CCU) of the MBC 805 receives a complaint, it is entered into a tracking database and assessed by an analyst. See the Manual of Model Disciplinary Orders and Disciplinary Guidelines in Appendix VII: Medical Board of California Documents. If the complaint is in the correct agency, the analyst determines the next step: 1) medical review related to standard of care; 2) technical violation; or 3) immediate investigation to a field/district office.

Medical review and technical offenses can have various outcomes, including referral to a field office for investigation, but they can also be closed if there is no violation (see Figure 4.4). When the CCU is

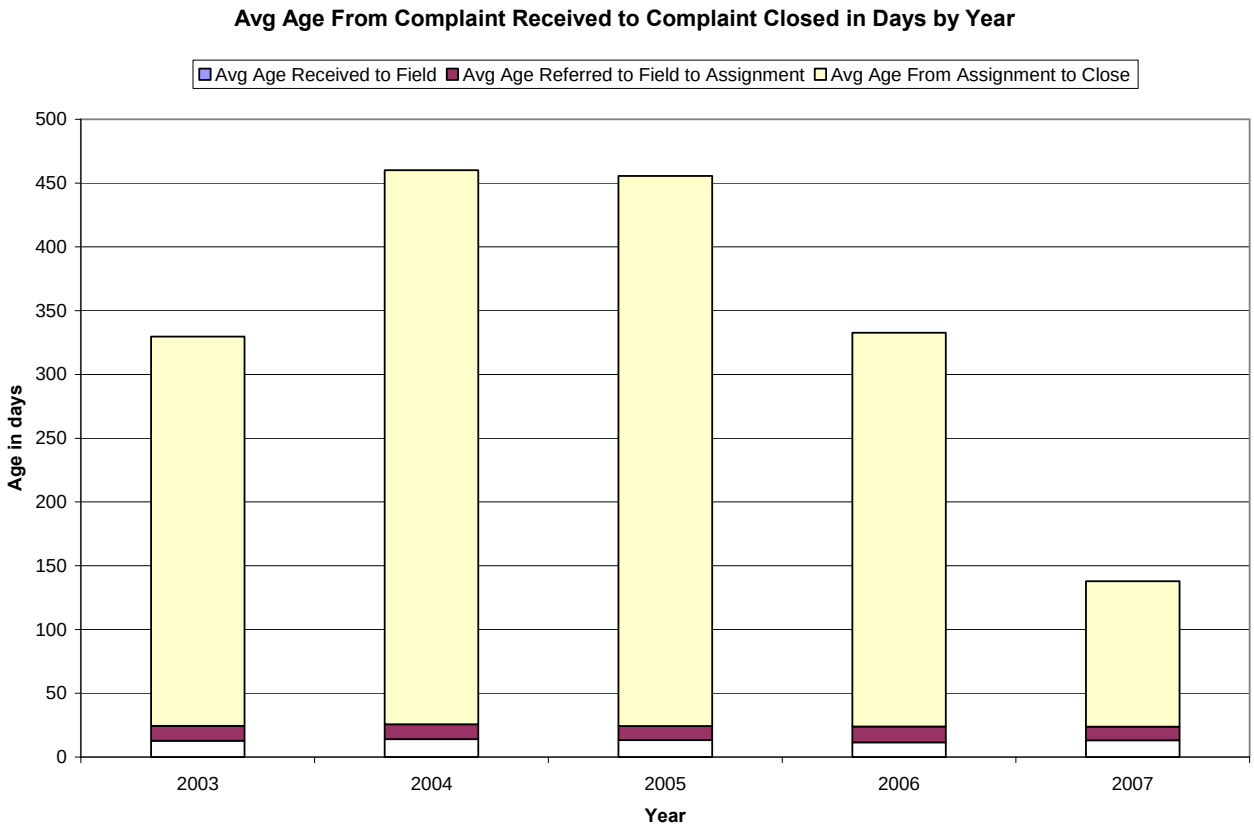
able to close the complaint without referring it to medical review or investigation, Figure 4.8 displays the average number of days to close it.

Figure 4.8: Average Number of Days - 805 Complaint Received at MBC → Closed in Central Complaint Unit



When the 805 is referred to a district/field office for investigation, the time naturally is extended. Figure 4.9 displays the average length of time the district/field office takes to receive the complaint, assign it for investigation, and close it.

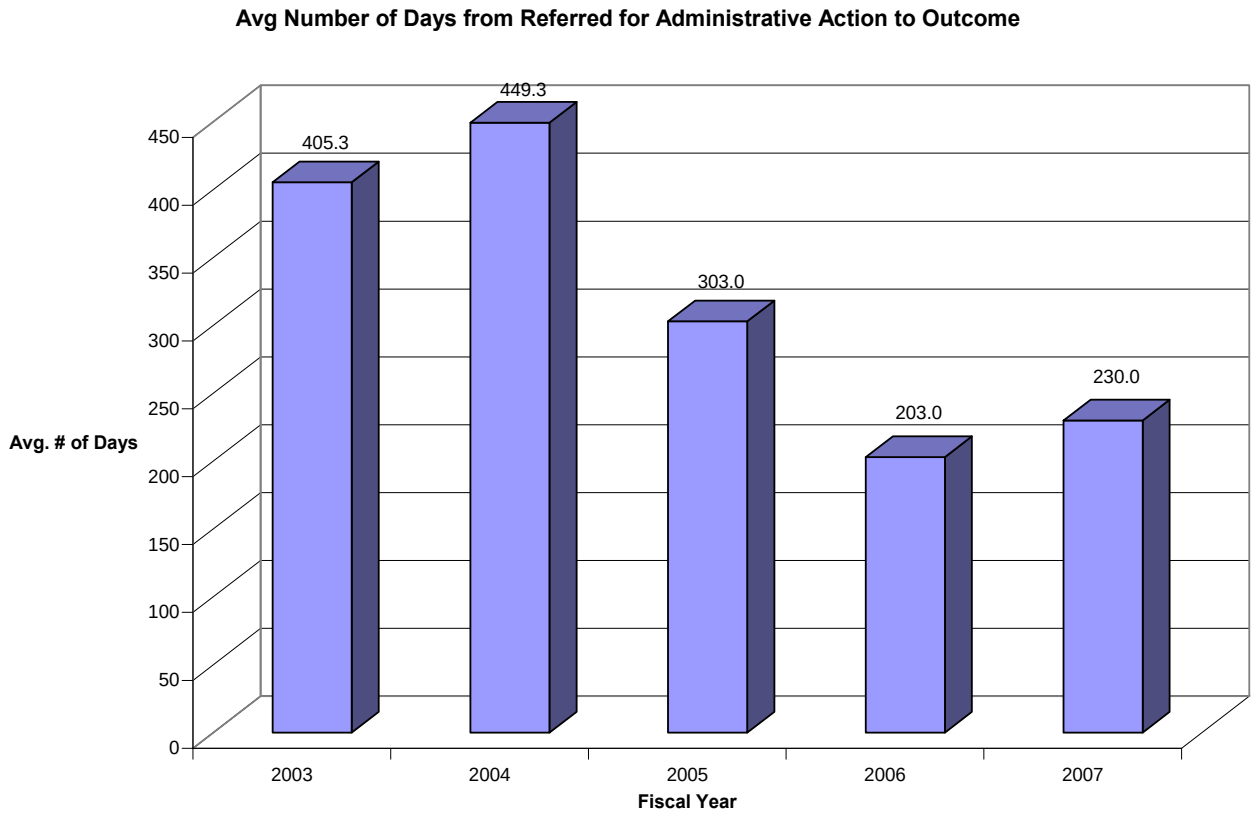
Figure 4.9: Average Number of Days - 805 Complaint Received by MBC → Referred for Field Investigation →Closed Complaint



In 2007, it took two weeks for an 805 to be referred from the CCU to a field/district office; 1½ weeks for an 805 to be assigned to an investigator; and three to four months to close the complaint in the field office. The time for investigation has declined since 2005, but it is still lengthy.

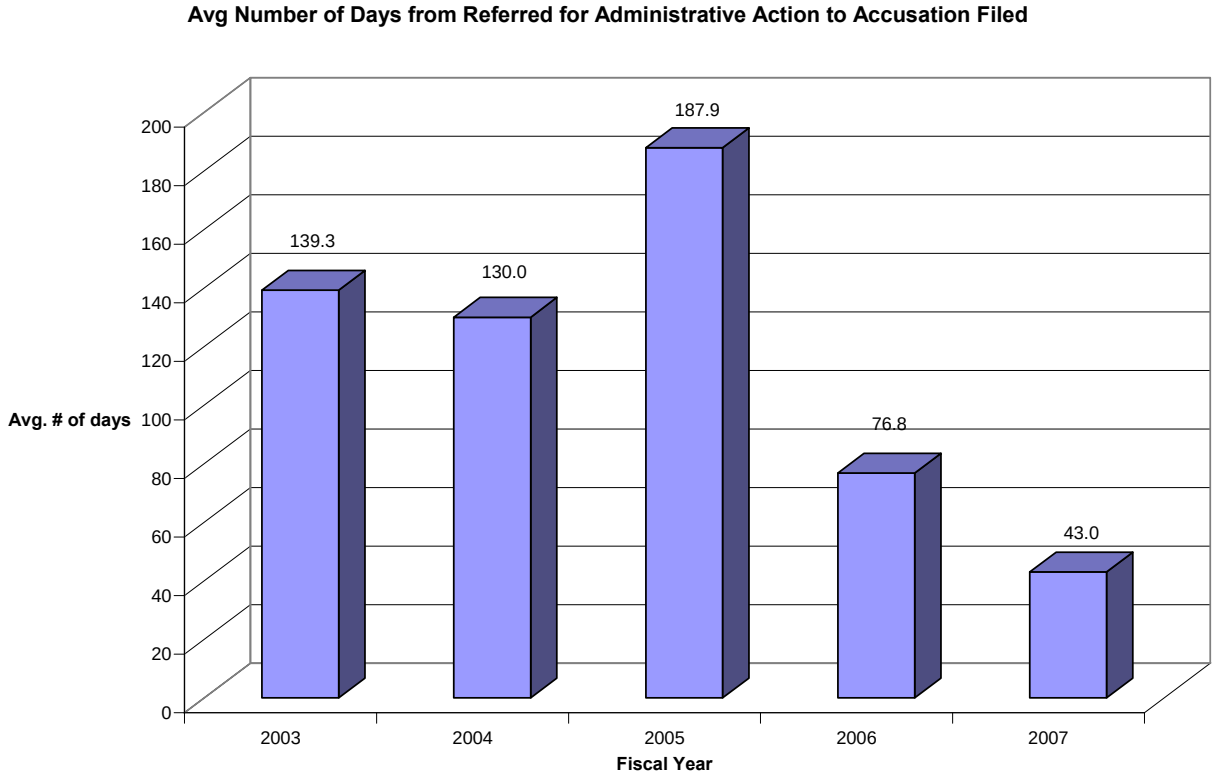
If warranted by the investigation, the 805 complaint is referred for "administrative action." Administrative action can include using sanctions against the physician's license to practice medicine by suspension or revocation, issuing citations for some violations of law, or requiring probation or monitoring. In 2007, the administrative action time averaged an additional seven to eight months (see Figure 4.10).

Figure 4.10: Average Number of Days - MBC Referred for Administrative Action → Outcome



Some issues are referred to the Attorney General's Health Quality Enforcement Section to determine whether to file disciplinary action, such as a formal accusation, which further extends the time. In 2007 the accusation filing took an additional six-plus weeks (see Figure 4.11).

Figure 4.11: Average Number of Days - MBC Referred for Administrative Action → Accusation Filed



Since the accused physician may continue to practice in some capacity throughout this time, it is easy to understand why the focus group participants and key informants reported that the MBC fails to take action or takes too long to take action. There are significant regulations that protect the rights of the physician, but the protections for the physician may conflict with the needs of the public.

Although survey respondents were moderately confident (3.6 on a 1-5 point scale) that the MBC would take action on an 805 that was submitted, focus group members disagreed. A number felt that the medical staff of various entities had become disheartened because MBC action was either absent or very delayed after an 805 was filed (see Figures 4.9 through 4.11, and Table 4.23).

Table 4.23: Online Survey - Confidence in MBC Action
(330 eligible respondents)

	n	Mean	sd
How confident are you that action will be taken by the MBC once an 805 report has been filed? (1 = Not confident - 5 = Very Confident)	225	3.6	1.3

FSMB Standard Seven: State medical boards should broaden the scope of investigation beyond the incident report or complaint…following screening, the investigation of quality of care cases not be limited to the incident…

The MBC is compelled to subpoena documents from entities when they need to investigate quality issues, and since the Dal Cielo ruling, key informants report that it is more difficult to obtain needed documents from hospitals[64].

FSMB Standard Eight: State medical boards should review their Medical Practice Act and pursue legislative support for statutory language to validate the board's subpoena authority and provide the board access to external peer review records.

It is our understanding that the MBC has sufficient subpoena authority to access records, but if the requirement for a subpoena is continued, in order to have a complete picture of events related to the complaint, the Board should broaden the scope of the subpoena to include **any** peer review records and other documents related to the history of behavior leading to the complaint.

FSMB Standard Nine: Based on findings, state medical boards should utilize distinct disciplinary tracks in the disposition of quality of care cases.

The MBC has various methods of discipline available (see Appendix VII: Medical Board of California Documents), including license suspension, license revocation, probation, or reprimand. The MBC also can order testing and examination and education, or dismiss the accusations. These decisions depend on the results of the investigation, but the State is deliberate in any investigation to revoke a medical license given that it is the property and mechanism of livelihood of the license holder.

FSMB Standard Ten: State medical boards should identify and utilize available means of physician assessment and remediation.

The MBC piloted the "Practitioner Remediation to Enhance Patient Safety (PREPS) Program" in 2001-02 with funding from the Health Resources and Services Administration. The goal of this program was to improve patient safety and the quality of care through the directed education and training of identified practitioners in need of remedial training. The Board also uses the Physician Assessment and Clinical Education (PACE) program at the University of California at San Diego School of Medicine, an assessment and skills remediation program in which many physicians disciplined by MBC are required to participate.

Although standards eleven and twelve are not applicable to this study, we list them below to show all the FSMB Standards.

FSMB Standard Eleven: The Federation should collaborate with other entities to develop standards for programs offering remedial medical education.

FSMB Standard Twelve: State medical boards should develop programs to enhance overall physician practice.

Requirement III Summary

Given the study time constraints, we focused on the 805 activities of the Medical Board of California, as they relate to Requirement III. Although other agencies and discipline-specific agencies exist, we found no systematic communication among them that involved coordination of patient quality and safety issues.

To assess the MBC in its management of 805 reporting, we applied the standards of the Federation of State Medical Boards (FSMB) of the United States, Inc. A summary of our findings regarding the MBC's performance follows.

- The MBC has numerous public information documents on its Web site (in both English and Spanish), but it is difficult for the general public to obtain the history of a particular physician.
- It is not clear that the Board receives valid and complete information from entities or individuals when investigating 805 reports, even with subpoena power.
- The Medical Board of California procedures for the complaint process, the enforcement process, and the public disclosure rules are complex and multi-layered.
- The investigation process of an 805 is slow as it moves through the MBC bureaucracy, from when the 805 is first referred to the MBC to closing or resolving the complaint.
- The MBC reports double digit vacancy rates for investigators because of workload and salary.

Requirement IV: An assessment of the cost of peer review to licentiates and the facilities that employ them.

We assessed costs of peer review using the survey, focus group, and key informant interview questions. We asked survey respondents to estimate both dollar and time costs to the entity and to individuals. Most respondents estimated that 0-250 hours were spent on peer review activities in the last calendar year (see Table 4.24). For entities that dealt with an 805 report, this likely added up to a significant cost in time for both physicians and support staff members.

Table 4.24: Online Survey - Total Time Spent for 805 or 821.5 Activities by Entity Role
(see below for eligible respondents)

	In the last calendar year, estimate the TOTAL AMOUNT of time IN HOURS spent by the following staff for 805 or 821.5 issues		TOTAL AMOUNT of time IN HOURS you lost from practice in related to being reviewed	TOTAL AMOUNT of time IN HOURS you spent related to your work as a physician reviewer	TOTAL AMOUNT of time IN HOURS you spent on behalf of the entity for 805 or 821.5 issues	TOTAL AMOUNT of time IN HOURS you spent in behalf of your clients for 805 or 821.5 issues
Hours	**Non MD Staff**	**Chairs only**	**Reviewed Physician**	**Physician Reviewer**	**Attorney for Entity**	**Attorney for Reviewed Physicians**
0-250 hours	75	19	11	53	13	0
251-500 hours	15	6	3	10	2	2
501-1000 hours	3	1	2	0	3	0
1000-3000 hours	3	0	2	3	0	0
Greater than 3000 hours	3	1	5	0	1	0
Total respondents	**99**	**27**	**23**	**66**	**19**	**2**
Eligible Respondents	**144**	**70**	**28**	**74**	**30**	**4**

Most survey respondents (69%) estimated that the cost of peer review in the last calendar year was between $0-50,000 to the entity, excluding physician costs in time, with 19% estimating $50-100,000 (see Table 4.25). Please note that is excluding physician time (i.e., the physicians who have privileges in the entity are volunteering their time in exchange for being able to use the facilities of the entity). This, of course, carries forward a practice that was begun over a hundred years ago when modern hospitals were begun. Fifty-seven percent of physicians who have been reviewed estimated the cost at $0-50,000 to the individual physician in the last calendar year (see Table 4.26).

Table 4.25: Online Survey - Total Cost of Entity for 805 or 821.9 Activities
(98 eligible respondents; 64 eligible respondents; percentages based on a denominator of 64)

In the last calendar year, estimate the TOTAL COST IN DOLLARS ($) spent by the entity on the 805 or 821.5 peer review process, including legal fees and all other time and staffing costs.	n	%
$ 0-50,000	44	68.8%
$ 50,001-250,000	12	18.8%
$ 250,001-500,000	1	1.6%
$ 500,000-1,000,000	4	6.3%
Greater than $1,000,000	3	4.7%
Total	**64**	**100.0%**

Table 4.26: Online Survey - Total Cost to Reviewed Physician for 805 or 821.9 Activities
(28 eligible respondents; 21 actual respondents; percentages based on a denominator of 21)

In the last calendar year, estimate the TOTAL COST IN DOLLARS ($) you spent being reviewed in an 805 or 821.5 peer review process, including legal fees and all other time and staffing costs.		%
$ 0-50,000	12	57.1%
$ 50,001-250,000	6	28.6%
$ 250,001-500,000	0	0.0%
$ 500,000-1,000,000	2	9.5%
Greater than $1,000,000	1	4.8%
Total	**21**	**100.0%**

There are different contractual arrangements between health plans and medical groups regarding responsibility for peer review. Some contracts place the burden of peer review on health plans and other contracts delegate peer review responsibilities to the medical group. Additionally some management service organizations (MSO) manage multiple medical groups and have contractual obligations to conduct peer review.

The variation in responsibility is a potential point of confusion; this point was verified during one of the focus groups. One participant commented that health plans depend on medical groups for peer review; a second participant said that medical groups depend on health plans; and a third person said both health plans and medical groups depend on hospitals. It became clear that entities did not want to be responsible for filing 805 reports and providing 809 hearings because of the cost, time, and contentiousness of the process.

Requirement IV Summary
In summary, our findings yielded the following about cost of the peer review process and its impact on the entities.

- In the last calendar year, an estimated 0-250 hours per individual physician reviewer, reviewed physician and attorney were spent on peer review activities.
- For 68% of survey respondents, the cost estimate in the last calendar year was between $0-50,000 to the entity, excluding physician costs in time, with 19% estimating $50-100,000,
- Costs to 57% of physicians who were reviewed were estimated at $0-50,000 to the individual physician.

Requirement V: An assessment of the time consumed by the average peer review proceeding, including the hearing provided pursuant to Section 809.2, and a description of any difficulties encountered by either licentiates or facilities in assembling peer review bodies or panels to participate in peer review decision making.

Survey respondents estimated 0-250 hours spent by the entity in the last calendar year on 809 hearings, keeping in mind that almost no entities had 809 hearings (see Table 4.27). Estimates by 86% of survey respondents for the cost of 809 hearings in the last calendar year were $0-50,000 for the entity (see Table 4.28). However, focus group participants estimated 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. One individual stated that an 809 hearing took months to complete because of scheduling problems, hundreds of thousands of dollars, and that one notorious hearing lasted for 17 years! (see Appendix IX: Comments About Study).

Table 4.27: Online Survey - Total Time Spent in 809 Hearings by Entities
(322 eligible respondents, 210 actual respondents, percentages based on a denominator of 210)

For the last calendar year, estimate the TOTAL AMOUNT of time IN HOURS spent by the entity on 809 hearings:	n	%
0-250 hours	196	93.3%
251-500 hours	9	4.3%
501-1000 hours	2	1.0%
1000-3000 hours	1	0.5%
Greater than 3000 hours	2	1.0%
Total	**210**	**100.0%**

Table 4.28: Online Survey - Total Cost of 809 Hearings by Entity
(214 eligible respondents; 124 actual respondents; percentages based on a denominator of 124)

For the last calendar year, estimate the TOTAL COST IN DOLLARS ($) spent by the entity on 809 hearings:	n	
$ 0-50,000	107	86.3%
$ 50,001-250,000	8	6.5%
$ 250,001-500,000	5	4.0%
$ 500,000-1,000,000	2	1.6%
Greater than $1,000,000	2	1.6%
Total	**124**	**100.0%**

Participants were asked to indicate the reasons they were willing to serve on peer review committees (see Table 4.29). Based on the responses most physicians serve on the committee because they are willing, they are interested and they have experience in peer review.

Table 4.29: Reasons for Serving on Peer Review Body
(74 eligible respondents, 64 actual respondents; percentages are based on a denominator of 64)

Identify the reason(s) you agreed to serve on the Peer Review Body? (check all that apply)	n	%
Willingness to serve	52	81.3%
Interest in peer review	46	71.9%
Experience in peer review	29	45.3%
Requirement for affiliation/employment	9	14.1%
Other	7	10.9%
Payment is offered by entity	4	6.3%
Scheduled/rotating obligation	3	4.7%
Requirement for hospital privileges	2	3.1%

When participants were asked to indicate potential reasons for non-participation (see Table 4.30), some respondents had comments such as, “conflict with other responsibilities,” “refused to agree to a confidentiality agreement,” “outside time constraints,” “all the above,” and “lack of experience” (see Appendix IX: Comments About Study).

Table 4.30: Reasons for Not Participating on Peer Review Body
(214 eligible respondents; 139 respondents; percentages based on denominator of 139)

Indicate reasons for non-participation	N	%
N/A	97	69.8%
Too busy	39	28.1%
Interferes with practice	19	71.9%
Do not like to judge colleagues	7	5.0%

We asked participants whether physicians were willing to serve on peer review committees if asked to do so (see Table 4.31). On average 4 (mean=4.1 sd=6.5) people were asked to serve last year with 1 declining (mean=1.1 sd-2.3) but as indicated by the standard deviation, there was substantial variation in the responses.

Table 4.31: Changes in Peer Review Members
(214 eligible respondents)

In the last calendar year:	n	Mean	sd
How many new members were added to the peer review body?	128	3	5.7
How many individuals were approached to serve on a peer review body?	101	4.1	6.5
If applicable, of those approached, how many refused?	73	1.1	2.3
How many unanticipated member changes have occurred in the peer review body?	127	0.5	1.1

Participants were asked to indicate the reasons for changes in peer review committee membership (see Table 4.32) and most changes were at the expiration of a regular term on the committee. However, over a quarter of the responses indicated that members just dropped out of the committee.

Table 4.32: Reasons for Changes in Peer Review Membership
(214 eligible respondents; 40 respondents; percentages based on denominator of 40)

If applicable, indicate the reason(s) for the changes	n	%
Term expired	20	50.0%
Member moved out of the area	11	27.5%
Dropout	11	27.5%
Member retired	4	10.0%
Moved practice	4	10.0%

Survey participants were asked about the efficiency and effectiveness of the 809 hearing process and reported that it was not efficient but was effective at ensuring physician rights (see Table 4.33). However, 68% (15 of 22) physicians who had been the subject of an 805 reported that they were not offered an 809 hearing (see Table 4.34).

This percentage is substantial and may reflect the confusion among entities about when an 809 hearing must be offered. Some participants understood that an 809 hearing must be offered before any 805 report; others thought it had to be offered before any 805 report, excluding a summary suspension or termination; and others did not know.

Table 4.33: Online Survey - Efficiency and Effectiveness of 809 Hearings
(322 eligible participants)

	n	Mean	sd
How efficient (in relation to timeliness and duration) was the 809 hearing process? (1=Not efficient - 5 = Very Efficient)	48	2.4	1.2
How effective (ensuring individual rights and that the process was followed) was the 809 hearing process? (1=Not Effective - 5 = Very Effective)	48	4.3	1.1

Table 4.34: Online Survey - Opportunity for 809 Hearings for Reviewed Physicians
(28 eligible participants; 22 actual respondents; percentages based on a denominator of 22)

Were you offered the opportunity for an 809 hearing?	n	%
Yes	7	31.8%
No	15	68.2%
Total	**22**	**100.0%**

We asked survey respondents which activities in the following table are required for an 809 hearing (see Table 4.35). The correct response is that all items (except none of the above) are required for an 809 hearing. Based on their responses, many respondents do not know the 809 requirements.

Table 4.35: Online Survey - Requirements of 809 Hearings
(350 eligible respondents; 222 actual respondents; percentages based on a denominator of 222)

Identify requirements of 809 hearings: (check all that apply)	n	%
An arbitrator(s) is selected by a process mutually acceptable to the licentiate and the peer review body or a panel of unbiased individuals, including an individual practicing in the same specialty as the licentiate, who shall gain no direct financial benefit from the outcome, who has not acted as an accuser, investigator, fact finder, or initial decision maker in the matter	161	72.5%
The right of the licentiate to inspect and copy relevant documents	156	70.3%
The parties shall exchange lists of witnesses at the request of either side	143	64.4%
Commencing a hearing within 60 days after receipt of the request	135	60.8%
The right of the licentiate to a reasonable opportunity to challenge the impartiality of the panel members and any hearing officer	128	57.7%
None of the above	45	20.3%

As a method of estimating costs to reviewed physicians and to discover if the peer review/805 processes were functioning as intended, we asked the entities to direct the survey to physicians who had been the subject of peer review (either favorable or unfavorable outcomes), and we also directly surveyed physicians who had been the subject of an 805 in calendar 2007. The responses of reviewed physicians were strikingly different from the responders who had not been the subject of an 805 report and different from the attorneys involved in the peer review/805 processes.

The 805-subject physicians described a process that was highly “political” and was used to eliminate competitors and eliminate peers, based on gender, ethnicity, language, psychiatric illnesses, "get rid of me," or just failure to fit into the culture of a particular medical staff. These 805-subject physicians described not being able to find any position or job after having an 805 report filed and spending three to five years in 809 hearings and other procedures to fight for their reputations, even after the MBC found no wrongdoing on their part. They reported spending thousands of dollars to fight the charges so they could again practice as physicians.

We asked respondents whether they felt the 805 was used for “political” purposes and the variance by who responded is considerable (see Table 4.36). Physicians who had experienced being reported via an 805 stated that having an 805 filed, especially if posted on the physician Web profile, was a “career ender” (see Appendix IX: Comments About Study).

Table 4.36: Online Survey - Use of Peer Review Reporting for Political Reasons
(350 eligible respondents)

How likely is it that 805 reporting is used for "political" reasons in your entity? Rate the following question on a scale of 1-5, with 1 being the least likely and 5 being the most likely .	**n**	**Mean**	**sd**
Peer Review Body Chair	44	1	0.2
Physician reviewer for the entity	62	1.1	0.4
Physician who has been reviewed	21	3.4	1.8
Non-physician entity staff	79	1	0
Attorney who has represented the entity in a peer	19	1.2	0.9
Attorney who has represented a physician being reviewed	2	1	0
Total	**227**	**1.3**	**0.9**

One might speculate that these were just "sour grapes" from physicians who had been caught practicing substandard medicine, but the vehemence with which these statements, phone calls, e-mails, and letters were made begs for further investigation and the question of whether at least some of these statements could be accurate.

Additionally, there are entities that support these physicians in their allegations against "sham peer review" (discussed in Chapter II: Background), such as The Center for Peer Review Justice, Inc. (http://www.peerreview.org/), the Semmelweis Society (http://www.semmelweissociety.net/), the Association of American Physicians and Surgeons, Inc. (http://www.aapsonline.org/), and the Alliance for Patient Safety (http://www.allianceforpatientsafety.org/). Again, it is easy to dismiss these entities and claims out of hand, but they raise questions that remain unanswered (see Appendix IX: Comments About Study).

We also asked survey respondents if they perceived any obstacles to the 805 or 821.9 reporting process. More than half of the respondents thought there were no obstacles. One-third were reluctant to take 805 action against a friend or colleague, and a quarter were reluctant to take 821.5 action. One-fifth of the respondents were fearful of being sued for restricting trade or some other potential retribution (see Table 4.37).

Table 4.37: Online Survey - Obstacles for Peer Review Reporting
(248 eligible respondents; 115 and 96 actual respondents; percentages based on a denominator of 115 (for 805 reporting) or 96 (for 821.5 reporting)

Indicate all obstacles applicable to each type of reporting (805 and 821.5) that you have experienced or would predict: (check all that apply)	805 reporting	%	821.5 reporting	%
No obstacles	48	41.7%	40	41.7%
Reluctance to take action against friend/colleague	39	33.9%	26	27.1%
Fear of being sued for restricting trade of a competitor	25	21.7%	16	16.7%
Reluctance to take action because of potential for retribution	23	20.0%	14	14.6%
N/A	15	13.0%	20	20.8%
Entity uses "internal punishment" (resignation, practice restriction) to reduce reporting	9	7.8%	3	3.1%
Entity encourages an "administrative resolution" (MD agrees to resign in exchange for the entity not filing a report)	9	7.8%	3	3.1%
Other	9	7.8%	5	5.2%

We also asked what recommendations people had to avoid the obstacles in the 805/821.5 process. Even though respondents recognized obstacles, 59% recommended that no change be made in the processes (see Table 4.38).

Table 4.38: Online Survey - Recommendations for Removing Peer Review Reporting Obstacles
(350 eligible respondents; 183 actual respondents; percentages based on a denominator of 183)

Indicate your recommendations to avoid the above obstacles: (check all that apply)	n	%
No changes necessary	108	59.0%
Independent body conducts the peer review (independent of the entity)	34	18.6%
Peer review to be completed by physicians outside the geographic area	33	18.0%
Other	25	13.7%
Non licensing body conducts the peer review (independent of state agencies)	11	6.0%

We asked respondents if they had recommendations to improve the peer review process. Most said no change was necessary, but about 20% suggested using an independent (non-government) agency to manage and conduct peer review (see Table 4.40). However, when we evaluated the responses to the question by entity role, we found only 19% of physicians who had been reviewed thought the process should not be changed, and the rest felt that some change should be made (see Table 4.39).

Interestingly, some of the attorneys in the focus groups thought that there was nothing about the 805 or 809 laws that needed to be changed; nothing was missing, and the language was clear and unambiguous. However, other focus group participants did not agree and made a number of suggestions for change/improvement, such as increasing education of the public and physicians about the peer review process, removing all blame from peer review and resolving patient care issues with physician education, or changing the peer review process to be more efficient.

Table 4.39: Online Survey - No Changes Necessary to Current Peer Review Process by Entity Role

Indicated "No Changes Necessary" to improve the current peer review process	Number Responding	Number Eligible	%
Peer Review Body Chair	33	42	78.6%
Physician reviewer for the entity	35	56	62.5%
Physician who has been reviewed	4	21	19.0%
Non-physician entity staff	58	74	78.4%
Attorney who has represented the entity in a peer	8	16	50.0%
Attorney who has represented a physician being reviewed	1	1	100.0%

Table 4.40: Online Survey - Recommendations for Improving the Current Peer Review Process
(350 eligible respondents; 210 actual respondents; percentages based on a denominator of 210)

Indicate your recommendations to improve the current peer review process: (check all that apply). These changes might relate to modernization, practicality, patient care, or transparency.	n	%
No changes necessary	139	66.2%
Hire an independent entity (non-government) to manage and conduct a peer review	41	19.5%
Other	21	10.0%
Create a statewide government entity that conducts peer review	10	4.8%
Create a statewide government entity that controls credentialing (not just licensing)	10	4.8%
Eliminate peer review	4	1.9%

In some committee minutes, we found indications that an entity would have repeated complaints/allegations against a particular physician without taking action against the individual. We asked survey respondents if that happened in their entity and one third said "yes." (see Table 4.41). When asked why that might happen, respondents checked "other" and provided comments (see Appendix IX: Comments About Study), such as the following two examples.

> "If the allegations are not substantiated, then the physician would be allowed to continue to practice. If the allegations are substantiated, then he/she would not be allowed to continue to practice. Unsubstantiated allegations would not be used to impose a practice restriction but that substantiated allegations would likely result in a practice restriction. The entity does not make peer review and quality decisions based on the amount of revenue a physician brings, on his or longevity with the entity or for any of the other reasons listed on the form."

> "The physician would be allowed to keep their privileges until such time the repeated allegations were investigated and substantiated. If the allegations posed immediate threat to patients the physician would be summarily suspended pending investigation." (see Table 4.42 and Appendix IX: Comments About Study).

Table 4.41: Online Survey - Continued Privileges for Providers with Repeated Allegations
(288 eligible participants; 169 actual respondents; percentages based on a denominator of 169)

In your entity, if repeated allegations are raised against a particular physician, would the entity allow this physician to maintain their practice privileges?	n	%
Yes	55	32.5%
No	114	67.5%
Total	**169**	**100.0%**

Table 4.42: Online Survey - Reasons to Allow Privileges for Providers with Repeated Allegations
(288 eligible participants; 107 actual respondents; percentages based on a denominator of 107)

Please identify potential reasons the entity would allow a physician with repeated allegations raised against them to maintain their practice privileges?	n	%
Other	57	53.3%
The entity would not allow such a physician to practice	30	28.0%
N/A	17	15.9%
The physician is the only specialist of a specific type in the geographic area	9	8.4%
The physician has been with the entity for many years	4	3.7%
The entity cannot find a replacement	4	3.7%
The physician brings in a large amount of revenue	2	1.9%
The physician admits many patients	2	1.9%
Total	**107**	**100.0%**

Requirement V Summary
In summary, our findings indicate that 805 reporting and 809 hearings are a major concern with respondents, not only in the associated costs (in dollars and time) of dealing with an 805 and 809 for both the entity and the affected physician, but also in the potential damage to one's career.

- Survey respondents estimated 0-250 hours and 0-$50,000 spent by the entity in the last calendar year on 809 hearings.
- 805-subject physicians described a peer review process with an agenda to rid entities of certain individuals for various reasons (e.g., ethnicity, gender, language, cultural misfit, etc.).
- 805-subject physicians described the lengthy process being embroiled in 809 hearings (3-5 years) and the difficulty in finding any job much less a physician position, even after MBC found no wrong-doing.

Study Validation Measures
We used a number of mechanisms to ensure the validity and reliability of our study methods and findings. In order to assure entity document evaluation reliability, all minutes, event summaries, and other submitted documents were reviewed by two study staff members; all data analyses were checked by two statistical analysts; data confidentiality was reviewed by a senior statistician; all e-mail comments and letters were reviewed by two staff members; and all focus groups were attended by two to three staff members.

Phase III of the study included site visits to 10 randomly selected entities from our initial site visit sample to check whether entity policies were being followed and to review documents that may not have been submitted. One entity indicated that they used an external audit company for some peer review cases, which extended the length of time required.

Two hospitals indicated that the peer reviews took longer than policies allowed. None of the site visit hospitals provided all the minutes and other documents requested. Two required the site visitor to sign a confidentiality agreement, and two required that she be accompanied at all times during the review. One recently purchased hospital claimed to have access only to peer review minutes that

occurred after the purchase (four months); one hospital only allowed her to review 805 reports with documentation. Given the limited access to documents, it is not clear whether the site visit hospitals are following the policies related to 805 reporting.

Two of the three medical groups and the health plan that were visited provided all documents requested. One medical group had access to only three years of minutes. The health plans and medical groups generally followed the policies and procedures and were meticulous about tracking credentialing. There was variability in tracking in hospitals. All health plans and medical groups used a categorization system that estimated severity of events that occurred and all used the MBC "hot sheets" to check on physicians.

For Phase V of the study, we randomly selected a different 5% sample of the initial sample to use for validation. In the first validation method, the study medical director reviewed patient records and decisions made by peer review committees in the sample entities. We were interested in determining if an independent reviewer would reach the same decision as the committee. Medical records or summaries of cases were made available for review by nine of the ten sampled entities. The entities submitted seven cases in which 805s were filed and five cases of quality concern without 805 filings.

Hospitals generally agreed to supply information on medical staff regulations including privileges, peer review, and disciplinary processes. Few details regarding the extent or nature of peer review were provided. Generally, there was only a brief summary of multiple cases of poor care by a physician, which resulted in a change/restriction/suspension of privileges and then 805 filing. Thus, it was impossible to determine the fairness of the processes for the physician or whether it was effective in eliminating poor care.

The cases demonstrating high level quality concerns (with no 805 filed) usually resulted from a single instance, and remedial actions such as education were prescribed. The role of the medical groups and health plan was generally passive except for removal of offending physician from their physician panel after a hospital filed an 805. They generally did not file the initial 805. The reviews for the individual entities follow.

Entity #1-Hospital (5 cases submitted; 4 with 805/1 not)
Hospital #1 provided copies of the Bylaws and Rules and Regulations of the Professional Staff. It included the investigation and corrective action practices as well as hearing and appeals procedures, including rules of evidence and burdens of proof. These were all separate from 805/809 State processes. Entity #1 then provided a brief summary of four cases for which 805 forms were submitted. Based on the information provided, the Lumetra reviewer found that grounds for filing and 805 were supportable.

Entity #1 also supplied a summary of a high-level quality concern that did not lead to 805. A peer review summary identified issues and MD counseling and educational efforts were planned. The Lumetra reviewer agreed with this decision based on information provided.

Entity #2-health plan (1 case; 0 with 805/1 without)
Entity #2 provided a credentialing department Medicare policy and procedure document, which included peer review committee function and responsibilities. Also noted is an affirmation statement that utilization decisions are based on medical necessity, and no discrimination or conflicts of interest are allowed. The process for filing an 805 is delineated, and the practitioner fair hearing documents are included as well. Peer Review committee minutes from 2006 - 2007 were included

and show the MBC hot sheet review and plan's responses. Entity #2 provided committee minutes of a quality concern that was raised and forwarded to the hospital. The Lumetra reviewer is not sure why this case was identified and reviewed, or what the eventual outcome was.

Entity #3-hospital (1 case; 0 with 805/1 without)
The entity filed no 805 cases in 2007, and there was only one high-level score case that year. A follow-up phone call was made to clarify, and the Lumetra reviewer agreed with the entity action. The entity also provided medical staff bylaws, rules, and regulations that detailed privileges and hearings but did not cite 805 notification or filings. Also included was an 805 report from December 2003, regarding a physician who withdrew his application for staff reappointment following notice of adverse recommendations. No clinical details or case information was provided in this filing.

Entity #4-hosptial (2 cases; 1 with an 805/1 without)
The entity submitted rules and regulations of the governing board, medical staff bylaws (even pages only), hearing procedures, general medical staff rules, and regulations. The entity reported the actions of the medical executive committee regarding the cases. In the first case, mandatory education was imposed first, then summary suspension, and finally termination.

The physician agreed not to practice at hospital pending a hearing and then resigned. This was reported as an 805 twice; first as a suspension and then as a resignation. The Lumetra reviewer agreed with the actions. The second case was a physician who allegedly had physical contact with an employee in the GI lab, which resulted in a two-day summary restriction of privileges to use the lab. The medical executive committee upheld the restriction and provided written warning, and no 805 was filed. The Lumetra reviewer agreed with the action.

Entity #5-medical group (2 cases; 1 with an 805/1 without)
The first example involved one physician and included committee minutes from May 2005 to October 2007 (nearly 2 ½ years). The events included eight case reviews and then ten more, multiple specialty reviews, letters to the physician, and finally termination. There was no information on any hospital actions or reviews during these years. The entity then filed an 805 after their attorney indicated agreement with the action.

The second example involved a physician who refused to see certain patients. The entity review indicated a practice with high compensation and poor patient access. The physician was terminated for not taking a board examination and violating medical group policy; no 805 was filed. The Lumetra reviewer agrees with these decisions.

Entity #6-hospital (4 cases submitted; 2 with 805 and 2 without)

The first example of an 805 event was the denial of reappointment because of failure to disclose suspension and resignation from a nearby hospital in 2005. The second example was a physician who had two years as a provisional staff member but continued to have a low surgical volume and needed additional proctoring. The physician took a leave of absence.

The first example of a non-805 event was two cases for a single physician without any apparent reason for review, peer review, or quality improvement evaluations. The second example was a patient seen in the Emergency Department twice on the same day and admitted; the patient was in jail and was admitted a second time upon release from jail. There was no information provided on the reason for review, peer review, or quality improvement evaluations. Based on very limited information, 805 filings appeared appropriate, and non-805 reviews had no obvious peer review cause for action.

Entity #7-professional society
This entity did not submit records because no peer reviews were performed in 2007.

Entity #8-hospital
This hospital did not submit records.

For the second part of this validation phase we selected a 5% sub sample (10 entities) of the entities and compared the survey responses submitted with the bylaws, policies, and procedures submitted by the entity. We reviewed seven hospitals, one health plan, one medical group and one professional society using a structured format (see Appendix IV: Structured Review Forms) and compared 11 variables.

Surveys from two entities were suspect in that only one person from each entity completed a survey and every response was checked "no" or there was no response. Therefore, these entities had no percentage agreement with the documents. In two entities (one medical group and one hospital) we found 90% agreement between the survey responses (both having six responses) and the documents for the items.

In three entities there was 64% agreement (two entities had one response and the other had one response); and in the last two entities there was 55% agreement in the responses (one entity had two responses and one had one response). These lower percent agreements may indicate that the survey respondents either did not know the entity policies or that the documents provided were not complete. There was one entity (hospital) that failed to provide any records. The high level of agreement between the Lumetra reviewer and the entity reviews provides evidence that some entities are complying with the policies and procedures and complying with the law.

Overall Summary

The overall study response rate for entities was 75.5% and the participants were a clear representation of the medical care entities in the State. Three hundred fifty individuals from 115 entities responded to the on-line survey. Each of the four entity types was represented in the survey respondents, with hospitals representing 62.9%. In summary, our findings revealed the following about "peer review," as it is conducted by entities in California:

1. Variation exists across entities in how they define and conduct "peer review."
    - There is wide variation in all aspects of the peer review/805 processes within different entities, including definition of the term "peer review," policies and procedures, tracking systems, infrastructure (i.e., review and decision-making committees) and responsibilities. Therefore, outcomes are highly variable and specific to each entity.

2. Overall, entities attempt to follow the letter of the law regarding 805 reporting (though perhaps not the spirit of the law).
    - Most entities routinely screen a certain percentage of patient records to check for evidence of substandard care.
    - The most common reasons for cases being referred for peer review to a high level (executive medical staff) committee are 1) disruptive physician behavior/impairment (821.5); 2) substandard technical skills; and 3) failure to document/record patient treatment.
    - Entities screened a large number of cases through the routine monitoring process. However, we estimate that a small percentage of routinely screened cases are forwarded to the

medical executive/decision making committee for further review and even smaller percentage results in an action that limits or terminates a physician's privileges for medical cause or reason, thus triggering an 805 report to the Medical Board.

3. 805 and 809 reporting is subject to interpretation, creates hardship for those affected (e.g., the entity and the physician), and allows many situations to go unresolved.
    - Peer review is lengthy, involving months or years of re-review, review of more records, interviews with the physician, and/or other investigation methods within the entity.
    - The peer review and 805/821.5 reporting processes in entities are highly variable; 805 reports are viewed as something to avoid; the 809 hearing process is inefficient but effective at preserving physician rights.
    - There is disagreement about whether an 809 hearing is required before an 805 report is submitted; 809 hearings for due process can add 2-5 years.
    - Some physicians are allowed to commit multiple disruptive actions over many years before any remediation is required, and it is possible that some physicians are never the subject of peer review.
    - The cost estimate of peer review in the last calendar year was between $0-100,000 to the entity, excluding physician costs in time, costs to physicians who were reviewed were estimated at $0-100,000 to the individual physician.

4. The Medical Board of California procedures for the complaint process, the enforcement process, and the public disclosure rules are complex, circuitous, and multi-layered.
    - The MBC has numerous public information documents on its Web site (in both English and Spanish), but it is difficult for the general public to obtain the history of a particular physician.
    - No systematic communication appears to exist among the various State boards and agencies that would coordinate patient quality and safety issues.
    - It is not clear that the Board receives valid and complete information from entities or individuals when investigating 805 reports, even with subpoena power.
    - The MBC investigation process is slow. In 2007, it took two weeks for an 805 to be referred from the central complaint unit to a field/district office, 1½ weeks for an 805 to be assigned to an investigator; and three to four months to close the complaint in the field office. An administrative action time averaged an additional 7-8 months; an accusation filing took an additional six plus weeks.

Chapter V: Conclusions and Recommendations

Introduction

Peer review and 805 reporting provide a process to review medical care, identify substandard medical care, develop ways to improve physician practice, and report certain events to the MBC for further investigation. The findings of the peer review study demonstrate that these processes have failed in their purpose to ensure the quality and safety of medical care in California. Rather, they allow entities to conduct medical peer review in a clandestine manner, so it is unknown whether the reviews are fair, whether the medical care is judged without bias, or whether or not physician practice is improved.

However, peer review and 805 reporting does succeed in creating the *appearance* of ensuring quality and safety of medical care by generally satisfying accreditation agencies (Joint Commission, Department of Health Services). The processes also cost significant healthcare dollars through actual dollars spent on legal fees, employee salaries, added staff members to ensure compliance with the numerous regulations and requirements, and State agency staff member salaries. Additionally, there are the opportunity costs consumed by these processes: time of physicians away from patient care or in lost off-work/family time; time used by hospital nurses and others in this complex and legalistic system that could be used in more productive patient care activities; and the time, pain, and suffering of patients who may experience injury or death in a system that does not protect them.

In this chapter, we present our conclusions and describe how our medical care quality and safety processes, including peer review and 805 reporting, are not supporting the citizens of California. We also provide for consideration by the MBC and the California legislature recommendations that would improve the peer review and 805 reporting system.

Conclusions

Requirement VI: An assessment of the need to amend Section 805 and Sections 809 to 809.8, inclusive, to ensure that they continue to be relevant to the actual conduct of peer review as described in paragraph (1), and to evaluate whether the current reporting requirement is yielding timely and accurate information to aid licensing boards in their responsibility to regulate and discipline healing arts practitioners when necessary, and to assure that peer review bodies function in the best interest of patient care.

The findings outlined in Chapter IV provide evidence supporting our conclusion that the peer review process, 805 and 821.5 reporting, and 809 hearings do not ensure quality and safety of medical care in California, for the following reasons:

- Excessive variation in policies
- Poor tracking systems
- Potential biased and ineffective reviews
- A too-lengthy process lacking transparency
- Groups of physicians who may never be peer-reviewed
- Burdensome costs to continue the current system

We explore these issues in greater depth in the following section.

Failures of Peer Review

Inconsistency of Peer Review Standards and Policies across Entities

All entities set their own standards for peer review, some more rigorous than others (see Figure 4.3), 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 provide substandard care, that physician may leave or be forced to leave that entity but can practice elsewhere, potentially endangering other patients.

Before a physician's privileges in an entity can be terminated, there is a lengthy (months or years) process during which the potentially substandard care continues to be provided. If an 805 or 821.5 report is eventually filed, there is another lengthy process of investigation designed to protect the legal rights of the physician. Thus, if the physician is providing substandard care, it could be years before a disciplinary action is ever taken.

Lack of Consistent Tracking of Peer Review Events in Entities

In the current system, there is either no tracking or no consistent tracking of peer review events in entities. A physician may have multiple events that indicate substandard care, but the entity has limited ability and resources for follow-up. Peer review events are generally documented within minutes of committees that serve many other functions, such as business functions, monitoring other disciplines, and other entity needs. The tracking of peer-reviewed events requiring entity investigation is buried in these minutes and depends on the persistence and commitment of key individuals in the entity to ensure that the tracking is done and brought back to the attention of the peer review committees.

Lack of Unbiased, Objective, and Confidential Review

Peer review is based on the assumption that the evaluation will be unbiased, objective, and confidential. These requirements are impossible to meet by a medical staff that works together, depends on each other, makes referrals to each other, and provides medical coverage for each other. External reviews are an option but are costly, and typically reserved for events for which the medical staff have limited or no expertise.

Implicit Peer Review Based on Fallacies

“Implicit" peer review (review done by a physician using individual judgment rather than criteria) is based on several fallacies: 1) The science does not exist to determine standards of care in a given situation; 2) You can have a standard based on one person's opinion; and 3) Only a physician can judge medical care. Implicit peer review is not acceptable in a day when there are standards based on science, and we are able to provide a more reliable system of review. At the very least, the reviews must be based on empirical evidence when that evidence exists.

No Standardization in Defining Events that Should Trigger Peer Review

Events, other than routine medical record review, can trigger peer review and lead to reporting, but those events are defined by each entity. There is some consistency in select entities because of requirements of voluntary accrediting agencies (Joint Commission, NCQA), but there is nothing that could be considered standardized. There is evidence from the survey that a number of respondents do not understand what should be reported to trigger a peer review, an 805 report, or an 821.5 report, and that most respondents depend on legal authority or malpractice insurance companies to decide whether or not to report to the MBC.

Lack of Transparency

The peer review and 805/821.5 processes lack transparency, and Evidence Code 1157 is used to protect the entity and the physician. Numerous laws and case law protect information that might harm the physician and entity through litigation. Neither the entity employees (other than the medical staff) nor the public has a right to information regarding peer review, since the activities are proprietary to the entity and are not "discoverable" legally.

Based on our survey and focus group respondents, the MBC is viewed by some as only intermittently responding to 805 reports, focusing particularly on those events that result in patient harm, unacceptably delaying the response, and not reporting public information. Additionally, the MBC is constrained by legislation that requires the agency to strictly limit public information related to 805 reports, including what and to whom the information can be disseminated, whether or not the information can be provided in hard copy, and how long the information can be left on the public Web site (see Table 2.10).

Entities frequently use attorneys to protect proprietary information under the guise of Evidence Code (EC) 1157. The conventional wisdom is that without Evidence Code 1157 protecting physicians from malpractice litigation, practice would not be discussed, mistakes would not be disclosed, and improvement in practice would never occur. Peer review would cease to exist. This assumes that physicians function primarily from the perspective of self-protection. However, because the current peer review system is so opaque, it is not clear what would occur without Evidence Code 1157.

Entities Avoid Following the “Spirit” of the 805 Law

Entities can take multiple steps to follow the letter but avoid the “spirit” of the 805 law by using tactics such as pressuring an offending physician to resign for reasons other than "medical cause or reason," by having summary suspensions less than 14 days, by negotiating with an offending physician privately through attorneys to avoid an 805 report, or by offering extended educational sessions and other remedial opportunities that would not trigger an 805 report.

Several participants reported that health plans and others faithfully review the MBC "Hot Sheets" to see if the MBC has taken an action against any physicians affiliated with their entity (although physicians are supposed to notify all their affiliate entities if an action against them is taken by the Board). If they see an affiliate physician, they then file an 805, although it is redundant and not required. It is reasonable that hospitals should take the major responsibility for peer review because of the rapid and significant injury to individuals that can be caused in the facilities. However, physicians who use hospitals also frequently are members of, or affiliated with, medical groups and health plans, so responsibility should be shared.

It is not ethical to use peer review and 805 reporting for purposes other than intended, such as ridding oneself of a competitor. Given the high rate of recidivism of drug and alcohol abuse, the lack of consistent record for tracking of 821.5 reports of physicians who have used drugs or alcohol, thus endangering patients, is entirely unacceptable.

Beyond initial entity credentialing for which the physician has responsibility, the entities have limited ability or motivation for removing unsafe physicians from the staff. Routine re-credentialing and peer review were designed to be part of the patient quality/safety system, but responsibility rests with the entity to trigger re-credentialing and peer review.

Not All Entities Perform Peer Review

There are medical groups/clinics and health plans that are not required to perform peer review because they do not meet one of the myriad laws defining which entities must report to the MBC. Also, all health plans, medical groups/clinics, ambulatory care centers, outpatient surgery centers, and other facilities where medical treatment is performed and injury to the public can occur, are not licensed by the State, and all physicians are not required to undergo peer review or some type of quality assessment.

Also, the California codes are unclear as to whether an 805 must be reported only after an 809 hearing or can be filed before a hearing; or whether an 809 hearing is only required prior to an 805 when there has been a summary suspension of greater than 14 days or a termination.

Extensive Delays Create Barriers to Public Protection

The delays in the process are extensive and serve as a barrier to the goal of protecting the public. Entity delays through poor tracking, ownership change, hospital staff turnover, reluctance of medical staff to discipline a colleague, ignoring physician behavior, and MBC delays for investigation and decision making and multiple other reasons render the processes impotent in investigating past injury and preventing future injury.

Costs Related to Processes are Prohibitive

The costs of 805, 821.5, and 809 processes are prohibitive, and entities and physicians use all possible means to avoid the time and money that are involved in the lengthy, contentious processes. Some hospitals have suggested that the offending physician split the hospital costs with the entity in addition to the physician's cost of hiring a private attorney and time lost in income.

In summary, these failures of the peer review, 805/821.5, and 809 hearing processes to ensure patient safety call for major changes to the current system. In the following section, we propose recommendations to correct these issues, specifically addressing the last four requirements (VII, VIII, IV, X) of the 805.2 legislation related to recommended changes. Although the legislation asks for what appear to be moderate changes and suggestions to current codes, we recommend major changes and improvements to the peer review/805 system because it cannot be "fixed" with moderate changes.

Requirement VII: Recommendations of additional mechanisms to stimulate the appropriate reporting of peer review actions under Section 805.

As we have indicated, although the entities in the study follow the letter of the 805 reporting law. Recommendations 2, 3, 4, and 5 address changes that would improve the reporting process.

Requirement VIII: Recommendations regarding the Section 809 hearing process to improve its overall effectiveness and efficiency.

The 809 hearing process is rarely used because 805 reports are relatively rare, and the process is inefficient, costly and legalistic, requiring many hours of physician and entity staff time, thousands of dollars, and extensive services of attorneys. Recommendation 7 addresses changes needed to improve the process.

Requirement IX: An assessment of the role of medical professionals, using professionals who are experts and are actively practicing medicine in this State, to review and investigate for the protection of consumers, allegations of substandard practice or professional misconduct.

Creating a system requiring physicians to provide objective and independent review of colleague friends or enemies is an unrealistic expectation. Recommendations 2, 3, 4, 5, and 7 provide a mechanism to engage experts who are practicing medicine in the State and who can be objective, independent and unbiased reviewers. As mentioned, all physicians could be required to provide this service as a requirement of licensure.

Requirement X: An assessment of the process to identify and retain a medical professional with sufficient expertise to review allegations of substandard practice or professional misconduct by a physician and surgeon, if the peer review process is discontinued.

As mentioned previously, Recommendations 2, 3, 4, 5, and 7 provide mechanisms to engage experts who are practicing medicine in the State and who can be objective, independent, and unbiased reviewers. The State could either pay the physicians or require this service as a condition of licensure. Because we have found evidence that the current peer review process, the 805 reporting process, the 821.5 process, and the 809 process are ineffective and inefficient in protecting the public health, we enumerate recommendations to change and improve the entire system.

Recommendations

1. Re-design the peer review process and create an independent review organization [addressing 805.2 (6), (7), (8), (9), & (10)]. Based on the analyses of all data, we recommend that the MBC and legislature change the peer review process in the following ways:
    - Continue to allow healthcare entities to provide first level quality/safety screening of physician practice through random record review of each physician no fewer than twice every year.
    - Define specifically what is required in the first level screens; these could be screens recommended by a professional accrediting agency.

- Refer any physician whose actions related to patient care do not meet the standard of care of the screening, or "fall out" of the screens for any reason, to an unbiased independent peer review organization that has no vested interest in the review outcome except protection of the public.
- The independent organization will be selected by the MBC or the appropriate legislative committee. All further responsibility for making decisions about taking any action toward the physician including 805 or 821.5 reporting would be removed from the healthcare entity.
- After the initial identification by the healthcare entity, the independent organization would take over all further investigation of the issue and make a recommendation to the healthcare entity regarding either filing an 805 report or other action such as recommending physician education and training, recommending PACE (UCSD Physician Assessment and Clinical Education Program, or recommending anger management training. A copy of all recommendations would be sent to the MBC. The healthcare entity would decide to follow or not follow the recommendation.

    - If a healthcare entity has an event (serious event or sentinel event) that requires an expedited or "fast track" review, that event would be reported to the independent entity within five hours. The independent organization would expedite the review/investigation (no longer than three days) and make an action recommendation to the MBC and to the healthcare entity (805, summary suspension if not already imposed, or other action).

    - The independent organization would create a tracking system to follow patient-related care issues by physician over time to monitor trends.

    - If a physician is not affiliated with an entity that performs peer review, the physician is responsible for initiating peer review at least twice annually through a professional entity. There would be substantial financial penalties for failing to being subject to peer review twice annually.

    - All patient, physician, or employee complaints related to patient care would be referred by the healthcare entity to the independent entity for investigation.

    - The independent organization would randomly select entities for assessment of the initial peer review process no fewer than once every three years. The independent entity would perform site audits of quality and safety programs, similar to Medi-Cal site audits.

2. Improve transparency [addressing 805.2 (6), (7), (8), (9), & (10)]
    - MBC would notify complainant and subject immediately when investigation is begun, when the information goes on Web site, and when it is taken off the Web site.
    - The independent entity would be blinded to physician name (using the national ID number). The MBC would be aware of all identifying information.
    - The MBC would increase transparency of reporting to the public by posting on the physician profile on the Web site any action recommendation (including history and outcome) by the independent entity and keep it there indefinitely.

- The MBC would create a user-friendly Web access so that a layperson can understand the sequence of events and find out whether the physician did or did not provide substandard care.

3. Revise role of the MBC [addressing 805.2 (6), (7), (8), (9), & (10)]
   - The independent entity would report all action recommendations to the MBC and to the entity.
   - The MBC would continue to investigate all 805 reports and make a determination about any license action and would be required to initiate an investigation within 48 hours of receiving an 805 report and make recommendations within five days of the completion of the investigation.
   - The responsibility of the 809 hearing would be removed from healthcare entities. The MBC or a designated independent organization would conduct 809 hearings to insure fairness.
   - Through the MBC, oversight for investigations, 809 hearings, and probation monitoring would be under the auspices of a "professional jury" composed of all practicing physicians. This "jury" service would be for a set time period and rotated among all licensed physicians in the State, being sure to only use people who did not have prior direct contact with the parties of the issue.
   - The legislature should either eliminate the requirement for a subpoena by the MBC to obtain needed documents from entities or the MBC should broaden the scope of any subpoena to include all documents related to the history of behavior leading to the complaint and any other relevant documents or medical records related to a patient care issue.

4. Emphasize credentialing [addressing 805.2 (6), (7), (8), (9), & (10)]
   - Routine credentialing and re-credentialing should still occur at the healthcare entity level. The healthcare entity would report any change in credentialing or privilege to practice to the independent entity. The independent entity would investigate and make a recommendation about whether an 805 or other action is warranted.
   - The physician would remain responsible for initiating any credentialing action.
   - The physician would be responsible for notifying the independent organization of any change in certification or credentialing by any professional group or healthcare entity. There would be substantial financial penalties for not reporting to the independent entity.

5. Promote education [addressing 805.2 (6), (7), and (8)]
   - The MBC should create mechanisms to continuously educate and update:

     a) All physicians and employees in entities required to file 805 reports, about the laws regarding peer review, 805, 821.5 and 809.

     b) All California citizens about their rights and how to use the MBC Web site.

     c) All entities about the requirement to not file redundant 805 reports.

6. Clarify codes [addressing 805.2 (6), (7), and (8)]
   - The MBC and 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.

- The MBC and legislature should clarify whether an 805 should be filed for not completing patient records.
- The MBC and legislature should require a consistent and separate tracking system of peer review activities over a five-year period, whether or not the entity is sold or changes ownership; require separate peer review minutes from all other committee or entity business.
- The MBC and legislature should create mechanisms to require all medical groups, clinics, ambulatory care, ambulatory surgical, health plans, and acute care hospitals to perform peer review and report to the MBC through the 805 mechanism.
- The MBC and legislature should create a mechanism to require every licensed physician to submit to peer review.
- The MBC should define peer review and define specifically events that would trigger peer review.

7. Identify Funding Sources

   Funding for the revised peer review system could be handled in a combination of ways without increasing taxes or diverting State funds, including:

   - Increasing physician license fees to support the process and a portion of those fees can be used.
   - Charging malpractice insurance companies a percentage of all policy payments they receive.
   - Attorneys for entities can provide a percentage of their billing income to fund the process.
   - Using a percentage of any malpractice judgment to help fund the process.

Pilot Study and Program Evaluation

Before full implementation of any change to the system, we strongly recommend that a pilot study be conducted, including process evaluations and outcomes evaluations related to patient safety and quality.

Evaluation of a program change is typically ignored because of many reasons, including the desire to be ignorant of the results. However, without a pilot program and an evaluation, the risk is that the change could cost much and gain nothing. With so much at stake in this potential change, every precaution must be taken to assure that the change will yield a great benefit in patient safety and quality. Prior to any change of this magnitude, comprehensive process evaluations must occur to ensure that the changed system is not just a recreation of the current system.

Finally, if there are any changes made, they must and should be phased in over a period of two to three years to provide for adjustment to the many affected systems.

Conclusion

There are negative aspects about the system of peer review and 805/821.5 reporting as mechanisms to ensure patient safety. However, there is one very positive aspect - the people in the system who try to make it function. The vast majority of individuals in the participating healthcare entities, the staff working at the MBC, and the people who provide legal counsel to organizations and individuals try to make this complex, bureaucratic, legalistically dysfunctional system work to protect patients by complying with the complex codes, laws, and regulations.

Multiple and conflicting demands require people to make difficult decisions that often in the end satisfy no one. One physician complained that he lay awake at night worrying that the peer review efforts for which he was responsible had allowed patients or physicians to be harmed. Many attorneys expressed frustration and anger that the system was not working properly, and healthcare administrators wished a better way existed to ensure patient safety and physician rights.

It would be easier and more expedient to make no change at all, and for many participants perhaps no change to the system would be better than changing to something uncertain. No change requires no further costs except to the citizens of California. It is the quality of care that would continue to be impacted by this flawed system.

With any major change to this century-plus old process, there will be widespread opposition from parties vested in the status quo or fearful that a new system might be worse. Based on evidence found in this study, change is imperative to protect the health and medical care of Californians, and it will require the help and support of the people who understand the nuances and complexities of the current system.

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Appendices