

How Peer Review Failed at
Redding Medical Center,
Why It Is Failing Across the Country
and What Can Be Done About It

DISASTER ANALYSIS REDDING MEDICAL CENTER
CONGRESSIONAL REPORT

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TABLE OF CONTENTS

Glossary	3
Executive Summary	4
The Authors and Our Goals	6
Redding Medical Center	7
▪ Period 1: Redding Medical Center 1993-1999: Physician Efforts to Stop Negligent Care at Redding Medical Center.....	8
▪ Period 2: 1999-2000: Surveys	10
– Surveys by California Department of Health Services Licensing and Certification Division and Joint Commission/California Medical Association-the Institute for Medical Quality	10
– California Department of Health Services Licensing and Certification Division First Resurvey	12
– California Department of Health Services Licensing and Certification Division Second Resurvey.....	14
▪ Period 3: Redding Medical Center 2000-2002: Physician Efforts to Stop Negligent Care at Redding Medical Center.....	18
▪ Period 4: 2002 Surveys Just Before the FBI Raid.....	21
▪ Other Reviews	23
▪ Period No.5: October 22, 2002	24
Case Reviews: A Widespread and Ongoing Problem	25
▪ Mercy Hospital (Sacramento).....	25
▪ Edgewater	25
▪ Western Medical Center	26
▪ University of Kansas Medical Center	26
▪ Garland Community Hospital.....	27
▪ New Hanover Regional Medical Center	27
National Practitioner Data Bank: An Ongoing Problem	28
Discussion and Remedies	32
Legislative and Agency Remedies	35

GLOSSARY:

CABG	Coronary arteries bypass graft (surgery) – surgery to bypass artery blockages that can cause a heart attack and death
CAD	Coronary artery disease – disease in the arteries that supply blood to the heart
CLIA	Clinical Laboratory Improvement Amendments
CMA	The California Medical Association—whose subsidiary is the Institute for Medical Quality
CMD	Medicare Contractor Medical Director
CMS	Centers for Medicare and Medicaid Services – the agency of HHS that administers the Medicare program and other federal health programs
COP	Condition of Participation—Medicare requirements to be a bona fide hospital provider
DHS	California Department of Health Services Licensing and Certification Division – in charge of hospital licensing
DMEPOS	Durable Medical Equipment, Prosthetics, Orthothotics, and Supply providers
FOIA	Freedom of Information Act – a way to get information from the government files
IMQ	The Institute for Medical Quality—company that reviews hospital activities for quality
IVUS	Intravascular ultrasound – a method to image the wall of an artery to check its thickness
JC	Joint Commission—formerly called the JCHAO, which accredits hospitals for a fee
MMA 2003	Medicare Modernization Act
POC	Plan of Correction – a plan to correct a problem, promised to California Department of Health Services Licensing and Certification Division
QIO	Quality Improvement Organization –A Centers for Medicare and Medicaid Services contractor that reviews hospital quality
RMC	Redding Medical Center: Redding Medical Center, Redding, California – where the disaster happened

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References in: Bold *italic* text

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EXECUTIVE SUMMARY

Physician peer review-American medicine's primary means of insuring high-quality patient care-is the oversight of physician practice within hospitals by the medical staff. It is designed to identify physician errors and opportunities for improvement and implement corrective action to assure safe and quality patient care. Oversight of the peer review process is so riddled with crippling flaws and the legislation governing the federal and state regulatory agencies so inadequate that prompt amendment of laws and regulations to protect the public is imperative. Without it, an indeterminate but undoubtedly large number of patients will needlessly suffer and die and the cost to Medicare and Medicaid will be exorbitant. The evidence for this grim assessment, some of which is provided below, is overwhelming. The problem, however, is not intractable. We offer a number of recommendations that we believe can substantially mitigate if not entirely cure the problem. To support our conclusions we also provide examples of failed or even nonexistent peer review compounded by inadequate oversight, and the frequently dire consequences that result, beginning with the unusually egregious case of Redding Medical Center.

For much of a ten-year period between 1992 and 2002, the cardiac program at this 240-bed, Tenet-owned hospital in Redding, a small city at the northern tip of California's Sacramento Valley, was performing an extraordinarily high number of cardiac procedures. These eye-catching statistics on catheterizations and coronary bypass operations were reported annually in the *Dartmouth Atlas of Health Care* and were well known to federal and state officials. Yet no agency sought as much as an explanation. It was not until 2002, when a skeptical heart patient called the FBI that an investigation began. One key finding that emerged from the investigation was that corporate officers, the administrators of Redding Medical Center, and the directors of the cardiology and cardiac surgery programs, Dr. Chae Hyun Moon and Dr. Fidel Realyvasquez, respectively, totally blocked peer review in the cardiac programs. As a result, hundreds of patients underwent unnecessary bypass and valve surgery from which some suffered debilitating injuries and others died.

The Redding case, while singular for the number of patients abused and the length of time it went on, is hardly unique. There is a long history of similar cases in which effective peer review and oversight could have made a difference (explained more thoroughly beginning on page 25).

In 1974, Judge B. Abbott Goldberg held an orthopedic surgeon named John Nork responsible for negligent surgery on a 32-year-old grocery clerk named Albert Gonzalez. During the trial Dr. Nork admitted to additional negligent and unnecessary operations. In a 196-page memorandum of decision, the judge concluded that at least 50 more surgeries might have been “*unnecessary, bungled or both.*” Throughout his opinion Judge Goldberg made reference to multiple occasions when Dr. Nork’s colleagues could have and should have blown the whistle.

For six years ending in 2001, physicians, administrators and management company executives at Edgewater Medical Center in Chicago conspired to defraud Medicare of tens of millions of dollars in a scheme that would have been impossible to implement had there been effective peer review and oversight. Dr. Andrew Cubria, a cardiologist, admitted performing unnecessary angioplasties and angiograms on more than 750 patients, two of whom died as a result of these unnecessary procedures.

Herbert A. Daniels, M.D., was found guilty in December of 2001 of 33 counts of healthcare fraud, seven counts of mail fraud and three counts of perjury dating back to 1986. Daniels was an ear, nose and throat specialist who performed surgery at the University of Kansas Medical Center, Bethany Medical Center and Providence Medical Center. According to the U.S. Attorney’s office, Daniels convinced patients to undergo unnecessary surgery to fill his surgical schedule resulting in bodily harm to at least one patient. Daniels was sentenced to six years in prison and his medical license was revoked, but it took 15 years and the involvement of federal law enforcement agencies to stop him.

When Dr. Steven E. Olchowski was granted a license to practice medicine in North Carolina in 1995, he had a 17-year history of alcoholism and psychiatric problems. He joined a surgical practice in Wilmington and began doing bariatric surgery at New Hanover Regional Medical Center. Eventually he was performing about 15 operations a week and bringing in millions of dollars in revenue. There were problems, though. He was billing for a complicated, but thoroughly tested procedure that is considered the gold standard. He actually performed short-cut operations that were not appropriate and not covered by insurance companies. There is evidence that both hospital administrators and the State Medical Board knew of his negligence but failed to stop him.

In each of these cases, effective peer review would have cut short the careers of these malefactors and saved innocent patients from having to undergo unnecessary invasive procedures, some of which caused permanent damage or even death. While peer review functions well in many hospitals-identifying opportunities for improvement, errors caused by mistake or gross negligence-there are structural problems that need to be addressed to improve the chances that it will work well everywhere.

As the Redding case demonstrates, a determined owner or administrator can frustrate the desire of the best-intentioned medical staff to institute effective peer review. Another problem is that most of the existing incentives discourage rather than encourage effective peer review. Reviewers lose time from their practice without compensation, they lose patient referrals from the physicians they review negatively, and they are often

characterized by colleagues as being on a “*witch hunt*” or having ulterior motives such as to get rid of a competitor. Also, if the physician reviewed is a major source of revenue for the hospital, a reviewer who finds fault might lose grace with the administration.

Additional support for our conviction that peer review is too often inadequately implemented comes from the *National Practitioner’s Data Bank*, a federally mandated repository for reports on peer review actions when such action result in restriction or removal of a physician’s hospital privileges and malpractice settlements and awards. Based on an analysis of data bank records, about 4,000 instances of moderate to highly culpable physician errors are reported to the National Practitioner Data Base annually. However, only approximately 500 are reported by hospital peer review resulting in eight times as many reports of malpractice settlements and awards on moderate to highly culpable physician errors than on discipline resulting from peer review of those errors.

It wasn’t peer review alone that failed in Redding and elsewhere. The larger and more difficult problem, but also perhaps the one most susceptible to a legislative solution, is the failure of oversight. Even when it is performing optimally peer review is imperfect and requires a strong back-up system. This report examines why the government agencies, which are empowered to step in when peer review breaks down, are often ineffectual and it makes recommendation designed to prevent similar failures in the future. A variety of reasons have been cited to explain the apparent inability of the state and federal healthcare agencies to effectively monitor hospitals, including inadequate staffing and penalties that are poorly suited to achieving the desired goals. We evaluate these explanations with special reference to the suitability of the tools available to the regulators and the adequacy of staffing, and make suggestions which we believe can substantially improve oversight.

We also note that this report is neither exhaustive nor definitive. It is intended to help define the problem, underline the urgency of solving it, and offer guidelines toward a solution.

THE AUTHORS AND OUR GOALS

In order to prompt corrective action, the authors share a common belief that the Redding Medical Center disaster must be reported to the public so all may understand how our safeguard systems failed. These failures could be due to a “*dropped ball*” by an individual or department or due to inadequate oversight, regulations or statutes. In order to answer these questions, the cause of the Redding Medical Center disaster must be analyzed, which heretofore has not been done.

All three authors are licensed California physicians familiar with peer review and hospital quality control methods. Two served on the Redding Medical Center staff and one served as the Northern California Medicare Part B Medical Director during this period. The authors have no conflicts of interest to report. No compensation was paid or offered to any of the authors of this report. This report is provided as a professional service to our community in the hope the medical profession and our hospitals will improve peer review

and Congress will find methods to empower both. The result should be safer patient care within hospitals.

REDDING MEDICAL CENTER

In 1992, Redding Medical Center was one of two hospitals in Redding, a city of less than 80,000 inhabitants located in a vast but sparsely populated area of northern California. Both hospitals were about the same size—approximately 240 beds—and both were modern facilities. Mercy Medical Center was nonprofit while Redding Medical Center was owned by Tenet Corporation, a bottom-line oriented company that at the time was the nation's second largest for-profit chain. Each had an open-heart surgery program, but Redding Medical Center's was older and heavily advertised. The California Heart Institute, the program at Redding Medical Center, was bigger and far more profitable, accounting for about 40 per cent of the hospital's revenue. Despite its relatively small size and remote location, Redding Medical Center was one of Tenet's most profitable hospitals. The *Dartmouth Atlas of Health Care*¹, which tracks surgery statistics nationwide, reported that during the late 1990s and early 2000s Redding Medical Center's rate of coronary bypass surgeries per thousand Medicare patients was among the highest in the nation.

The directors of Redding Medical Center's cardiology and cardiac surgery departments respectively were Drs. Chae Hyun Moon, an uncertified cardiologist, and Fidel Realyvasquez, a Stanford University trained cardiac surgeon. These two physicians were the rainmakers for Redding Medical Center. Redding Medical Center rewarded them with annual six-figure salaries to serve as directors of their departments², (empty titles for which they effectively did nothing) in addition to their annual bountiful incomes from patient care. Redding Medical Center also reportedly guaranteed Dr. Realyvasquez a \$2 million annual income³ plus the exclusive right for his group to use the hospital for heart surgery. Dr. Realyvasquez could employ other heart surgeons, pay them a relatively low salary, and keep the profits.

Dr. Moon and Dr. Realyvasquez were the most powerful people on the medical staff and arguably in the entire hospital. By 2002, Dr. Moon and Dr. Realyvasquez were annually performing 4-5 times as many cardiac procedures and surgeries than would have been expected for the hospital and the population it served.⁴

Other physicians in Redding and as far as 200 miles away in the San Francisco Bay Area strongly suspected physicians at Redding Medical Center were performing unnecessary procedures and surgeries. Outside physicians filed seven complaints with the Medical Board of California based on findings from their patients who had been treated at Redding Medical Center. Redding Medical Center Medical staff physicians complained

¹ <http://www.dartmouthatlas.org/index.shtml>

² Directors typically are required to keep logs of their work in case of audit to prove the payment is not a kickback. The salaries at Redding Medical Center range from \$80,000 to \$150,000 annually. The tasks include efforts to improve quality, decrease resource utilization, and encourage referral of patients from other doctors. Dr. Moon eventually declined to accept the salary.

³ Dr. Moon told Dr. Sebat the amount of Dr. Realyvasquez's income guarantee and exclusivity provision.

⁴ Evidence from the *Dartmouth Atlas of Healthcare*.

to Redding Medical Center administrators beginning in 1996. No corrective action was taken until the FBI raid in 2002.

Evidence from the FBI raid showed that Dr. Moon, Dr. Realyvasquez, and associates performed unnecessary cardiac procedures on more than 600 patients between 1995 and 2002-damaging them physically and psychologically. Evidence from State and Centers for Medicare and Medicaid Services records shows that with help from Redding Medical Center administrators, Dr. Moon and Dr. Realyvasquez blocked peer review of their services and, thereby, successfully hid their negligence for 10 years.

PERIOD 1: REDDING MEDICAL CENTER 1993-1999: PHYSICIAN EFFORTS TO STOP NEGLIGENT CARE AT REDDING MEDICAL CENTER

Dr. Patrick Campbell was a young board-certified internist on the Staff at Redding Medical Center. Upon joining its medical staff in 1993, he was appointed to the Medical Records Committee. He promptly discovered that Dr. Moon had been subject to hospital suspension every single day of 1992 for failure to complete patients' medical records as required by Redding Medical Center medical staff by-laws. According to the by-laws, Dr. Moon should have been suspended from the medical staff and prevented from performing any elective admissions, consultations, or inpatient procedures. Rather than being restricted, Dr. Campbell discovered Dr. Moon was one of the busiest physicians at Redding Medical Center, performing as many as 2,000 invasive cardiology procedures annually.

Dr. Moon's production brought him power and influence within Redding Medical Center. In 1994, Redding Medical Center paid nurses to complete his medical records. Dr. Moon boasted in the doctor's lounge that he had more power than the CEO at Redding Medical Center. For example, during 1995, Mr. Gerald Knepp, CEO of Redding Medical Center upset Dr. Moon by recruiting an outside cardiologist for the Redding Medical Center emergency department call-panel. Dr. Moon complained to Tenet Corporation executives leaders. Thereafter, Mr. Neil Sorrentino and Mr. Tom Mackey of Tenet Corporation met with Knepp and Dr. Frank Sebat⁵, co-author of this report who at the time was a friend of Dr. Moon. Dr. Sebat verified that Dr. Moon was upset by Knepp's recruiting effort, which, if successful, would have taken away patient business from Dr. Moon. Shortly thereafter, Tenet removed Knepp as Redding Medical Center CEO.

Early in his practice career at RMC, Dr. Campbell referred one of his cardiac patients (M.R.) to Dr. Moon. Dr. Moon recommended coronary artery bypass and valve surgery. Dr. Campbell admitted the patient to the hospital for the surgery and a cardiac surgeon, Dr. Walter Schell, who Dr. Realyvasquez employed, unequivocally disagreed with Dr. Moon and found no need to operate. Dr. Campbell agreed with Dr. Schell. However, despite Dr. Schell and Dr. Campbell's objections, M.R. received coronary artery bypass graft surgery and a new artificial mitral valve. A few months later, M.R. died of complications of the surgery.

⁵ One of the authors.

After M.R.'s death, Dr. Moon cornered Dr. Campbell in a dictation room at Redding Medical Center. Dr. Moon chastised Dr. Campbell for disagreeing with his opinion, and for describing Dr. Moon to other physicians as too aggressive and too quick to recommend surgery. Dr. Moon's threatening manner intimidated and frightened Dr. Campbell.

In 1995, Dr. Campbell referred his patient E.M. to Dr. Tom Russ, a cardiologist who practiced in Dr. Moon's group. A stress nuclear cardiac scan to detect coronary artery disease was normal⁶, but, surprisingly, Dr. Russ recommended a cardiac catheterization of the arteries anyway. On June 15, 1995, Russ informed Dr. Campbell by telephone that the catheterization showed severe three-vessel coronary artery disease, including a ruptured atherosclerotic plaque in the left anterior descending coronary artery. Dr. Russ recommended immediate coronary artery bypass graft surgery. Dr. Realyvasquez performed the bypass surgery on June 16, 1995. Two months later, on August 28, 1995, Dr. Russ dictated his written report of E.M.'s catheterization. Contrary to his verbal report to Dr. Campbell, Dr. Russ's written report described only minor blockages in the three major coronary arteries and concluded that surgery was not needed.

The discrepancy worried Dr. Campbell so he asked an independent cardiologist, Dr. Roy Ditchey, to review the catheterization films without telling the full story. Dr. Ditchey confirmed the minimal findings Dr. Russ reported and verified only medical treatment was necessary. When Dr. Campbell told Dr. Ditchey that E.M. had surgery, Dr. Ditchey was surprised, particularly because Dr. Realyvasquez, the cardiac surgeon, should have checked the cardiac catheterization images personally before operating and discovered the blockages were minor and did not require surgery.

From these two cases, Dr. Campbell concluded his patients had been inappropriately subjected to catheterizations followed by unnecessary heart surgery. One had died as a result. Dr. Campbell was distressed over Dr. Realyvasquez and Dr. Moon's seemingly appalling and possibly criminal behavior. Dr. Campbell struggled to believe that respected physicians and directors of their departments would negligently and deliberately harm patients.

In May 1997, Drs. Campbell, Bruce Kittrick, Gary Crawford and Dinesh Mantri, all internists, met formally with Ken Rivers, then CEO of Redding Medical Center, in the Liberty Conference Room at Redding Medical Center. The doctors complained about inaccurate reports of cardiac catheterization that led to unnecessary cardiac surgery. The doctors proposed Redding Medical Center hire outside experts to review the images and compare them to Dr. Moon's written reports. Rivers did nothing. Later, in November 1997, Dr. Campbell mentioned their request to Rivers a second time. Rivers appeared flustered claiming he had forgotten the matter. The outside review of Dr. Moon's work was never performed.⁷

⁶ A negative stress nuclear scan strongly supports the absence of coronary disease so that the invasive and more risky coronary artery catheterization procedure may be avoided.

⁷ This outside peer review action would have identified the negligence by Dr. Moon and Dr. Realyvasquez.

In 1999, cardiologists Dr. Robert Pick, Dr. Roy Ditchey, Dr. Michael Stewart and oncologist Dr. Thomas Drakes complained about unnecessary cardiac procedures and/or surgeries to Mr. Steven Schmidt, the CEO of Redding Medical Center, Mr. Hal Chilton, Schmidt's successor. Dr. Pick demanded an independent review of cases focusing on the accuracy of Dr. Moon's diagnoses. Redding Medical Center administrators refused. Dr. Stewart, who also worked at another Redding hospital, Mercy Medical Center, told Chilton that he needed to run "*an honest shop.*" Anesthesiologist and Chief of Staff Dr. Leonard Soloniuk asked Schmidt to support the medical staff's recommendation to suspend Dr. Moon and Dr. Realyvasquez elective privileges for habitually inadequate medical recordkeeping. Schmidt refused.

PERIOD 2: 1999-2000: SURVEYS

During the spring and summer of 1999, Redding Medical Center underwent four inspections (called surveys), three by state investigators under the Licensing and Certification (L&C) Division of the State of California Department of Health Services and one by Joint Commission surveyors with assistance from physicians who worked for the California Medical Association's Institute for Medical Quality.

SURVEYS BY DHS AND JC/CMA-IMQ

On June 10, 1999 the California Department of Health Services Licensing and Certification Division conducted its routine⁸ survey of Redding Medical Center. The survey was not prompted by complaints about Redding Medical Center. California Department of Health Services Licensing and Certification Division found three violations: Title XXII §70433(a)(2), §70433(j), and §70701(a)(7). The State found Redding Medical Center failed to regularly review cardiovascular surgery cases, both preoperatively and postoperatively, and failed to implement proper quality controls. It further found that the medical staff did not consider a serious adverse patient care event caused by a cardiovascular surgeon when reappointing that physician to the medical staff.⁹

In response to these deficiencies, Redding Medical Center established a Plan of Correction. To correct its violation of §70433(a)(2), Redding Medical Center proposed the Surgical Care Committee Chairman would review outstanding peer review cases and report to Surgical Care/Surgical Executive Committees by August, 1999. Any significant cases needing specialist review would be referred to outside peer review conducted by Stanford University, where Dr. Realyvasquez had trained. Discussion, recommendations, and actions would be recorded in appropriate minutes and reported to the Medical Staff Executive Committee. The quality profiles would be reviewed by the Quality Management Coordinators to highlight any peer review issues that needed to be addressed by the appropriate department chiefs prior to a recommendation for reappointment. The department chiefs would specifically comment on any untoward event identified before a reappointment. Mr. Mark Eliason, Redding Medical Center

⁸ Done once every three years.

⁹ Dr. Realyvasquez was in charge of reappointment of physicians within his department and the physician to be reappointed was employed by Dr. Realyvasquez.

Quality Manager, and Ms. Michelle Hammer, the Medical Staff Coordinator, were responsible for the plan. The completion date was August, 1999.

Concurrently but independently the Joint Commission and the California Medical Association's Institute for Medical Quality inspected Redding Medical Center. Both of these non-government organizations found the same peer review deficiencies, which also violated Joint Commission's accreditation standards. Two of five physician credential profiles in the cardiac program contained numerous significant iatrogenic¹⁰ complications. These cases were not reviewed and these two physicians were reappointed to the medical staff without comment.¹¹

Although Joint Commission asked Redding Medical Center to correct these peer review deficiencies, it immediately accredited Redding Medical Center for three more years: from June 19, 1999 until June, 2002. The Joint Commission did require Redding Medical Center to report on its correction of its peer review deficiency within 6 months.¹² The Joint Commission and the Institute for Medical Quality refused to provide us with Redding Medical Center's report.¹³ We know from the State records however, that Redding Medical Center's Administration and Board of Directors never required the medical staff to conduct the required peer review and never met the Joint Commission accreditation standards. Nonetheless, Redding Medical Center was able to advertise its accredited status to promote a high quality image to the public.

After its June 1999 findings, California Department of Health Services Licensing and Certification Division reported Redding Medical Center's deficiencies to Wayne Moon (WM) (no relation to Dr. Moon). WM was the Director of Hospital and Community Care Operations for the Centers for Medicare and Medicaid Services, San Francisco Regional Office. WM was responsible for hospital provider credentialing. WM authorized California Department of Health Services Licensing and Certification Division to resurvey Redding Medical Center, this time for violations of federal requirements:

¹⁰ An adverse event caused by the physician.

¹¹ Standard # MS.5.4.5 from the *Comprehensive Accreditation Manual for Hospitals*

¹² The Joint Commission letter was on file with California Department of Health Services Licensing and Certification Division by accident. California Department of Health Services Licensing and Certification Division gave us a copy of the document.

¹³ The Joint Commission findings during their accreditation survey were confidential in 1999 and remain confidential. Private organizations are not subject to Freedom of Information Act requests. The Joint Commission has *deemed status* which means Centers for Medicare and Medicaid Services accepts without question the Joint Commission survey findings as evidence the federal standards of quality, set forth under the Medicare Conditions of Participation, are met. Centers for Medicare and Medicaid Services must accept Joint Commission's findings without review, unless a state survey, a patient, or a physician reports to Centers for Medicare and Medicaid Services a danger sufficiently worrisome that it asks the State to perform a survey. According to the Center for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification, neither organization requested to receive the Joint Commission findings regarding Redding Medical Center. The Joint Commission accreditation is voluntary and is paid by Joint Commission client hospitals, which creates a potential conflict of interest. 42 U.S.C. § 1395 bb provides deemed status to the Joint Commission.

Medicare Conditions of Participation. Violation of a Condition of Participation jeopardizes a hospital's provider status with the Medicare program.¹⁴

DHS First Resurvey

California Department of Health Services Licensing and Certification Division conducted a resurvey as an agent for Centers for Medicare and Medicaid Services on July 14, 1999. California Department of Health Services Licensing and Certification Division found that Redding Medical Center did not provide a hospital-wide quality assurance program required under federal Medicare Conditions of Participation 42 CFR 482.21(a), 42 CFR 482.21(c)¹⁵, and 42 CFR 482.22(a)¹⁶. Redding Medical Center's Board of Directors refused to compel and the administration interfered with its medical staff to review the behavior of Dr. Moon, Dr. Realyvasquez, and their associates. Specifically, California Department of Health Services Licensing and Certification Division found:

- There was no physician (peer) review of the cardiovascular surgery patients that had serious postoperative and intra-operative events.
- Seven death cases beginning 6/27/1997 had not been reviewed.
- The responsible medical staff physicians refused to do the chart reviews.
- The hospital medical staff had not carried out its responsibility to assure that quality medical care was provided to all the patients in the hospital.
- The medical staff had been unable to conduct comprehensive appraisals of the cardiovascular surgeons and of the cardiovascular services.
- The medical staff had not been accountable to the governing body for the quality of the medical care provided to Redding Medical Center patients.¹⁷

¹⁴ On average, hospitals earn about 50 per cent of their revenue from the Medicare program. If its provider status is lost, Medicare would not pay Redding Medical Center for all services provided to Medicare patients. However, Centers for Medicare and Medicaid Services has no authority to impose intermediate sanctions in order to deny payment for selected services. For example, in 1999 and today, Centers for Medicare and Medicaid Services cannot deny payment for care until adequate peer review is implemented in that service. We will return to this issue in our recommendations.

¹⁵ (c) **Standard: Program Activities.** (1) The hospital must set priorities for its performance improvement activities that— (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety, and quality of care. (2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital. (3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

¹⁶ The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. (a) **Standard: Composition of the Medical Staff.** The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body. (1) The medical staff must periodically conduct appraisals of its members. (2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

¹⁷ State Survey documents on Health Care Financing Administration 2567 forms discovered pursuant to our Freedom of Information Act request.

In response to the July California Department of Health Services Licensing and Certification Division survey, Redding Medical Center proposed a Plan of Correction to be completed by August 13, 1999:

- Its Medical Staff Quality Committee would monitor all peer review activities for timeliness and effectiveness as a regular agenda item.¹⁸
- Delays in the physician peer review greater than four weeks from the date of assignment or any peer review deemed incomplete would prompt medical staff leadership intervention.
- The Medical Staff Executive Committee would review the peer review process and approve the assignment of the cardiovascular peer reviews to the sub-specialists in the cardiovascular subsection via the Surgical Care Committee.
- Redding Medical Center proposed to pursue an agreement to have peer review performed by a physician from outside the community for any cases requiring specialized expertise or where it determined that the case cannot be adequately evaluated internally.

Redding Medical Center reiterated in an August 26, 1999 letter sent to Mr. Robert Kennard (District Administrator for California Department of Health Services Licensing and Certification Division Licensing and Certification, Chico, California) its plan to correct the deficiencies which California Department of Health Services Licensing and Certification Division discovered in its July survey.

On September 3, 1999, Centers for Medicare and Medicaid Services, Wayne Moon wrote to Mr. Steve Schmidt, CEO of Redding Medical Center stating that Redding Medical Center still did not comply with Medicare requirements set forth in Quality assessment and performance improvement program (quality assurance) and 42 CFR 482.22 (Medical Staff). WM stated that these violations “*substantially limited*” the capacity of Redding Medical Center “*to provide adequate care.*” As a result, Centers for Medicare and Medicaid Services removed Redding Medical Center’s status as a provider deemed to meet Medicare Condition of Participation which placed Redding Medical Center under the California Department of Health Services Licensing and Certification Division survey jurisdiction until Redding Medical Center could demonstrate full compliance with the Medicare Conditions of Participation.^{19 20 21} In response to the Centers for Medicare and Medicaid Services action, Schmidt reiterated Redding Medical Center’s Plan of Correction in his September 28, 1999 letter to WM. A copy of the plan was sent to Mr.

¹⁸ Redding Medical Center claimed the Quality Committee was not protected by California State Evidence Code §1157 and therefore was not permitted to review medical records. The Quality Committee could only determine whether the peer review committees were performing their work, based on self-reporting. Redding Medical Center’s interpretation of the law was false.

¹⁹ Freedom of Information Act discovery.

²⁰ Centers for Medicare and Medicaid Services authority is found in §1864 of the Social Security Act as amended by Public Law 92-603.

²¹ WM’s warning letter to Redding Medical Center did not affect its accreditation status given by Joint Commission. The Centers for Medicare and Medicaid Services letter warning of Redding Medical Center’s limited capacity to provide adequate care was never made public. The patients did not know and reasonably could not have known that Redding Medical Center’s capacity to provide adequate care was substantially limited. The patients believed the opposite because Redding Medical Center was accredited and aggressively promoted its cardiac surgery low complication rate.

Robert G. Kennard for California Department of Health Services Licensing and Certification Division.²² Jan Chicoine of Redding Medical Center was responsible for the Plan of Correction.

DHS SECOND RESURVEY

California Department of Health Services Licensing and Certification Division returned to Redding Medical Center on October 21, 1999 to check its progress toward compliance. California Department of Health Services Licensing and Certification Division found Redding Medical Center continued to violate an element (054) of the federal standard contained in 42 CFR 482.21(a): Clinical Plan.²³

- The quality improvement studies of the Cardiovascular Surgery Service were not included in the hospital-wide quality improvement program.
- There were only two cardiovascular surgeons in this service.²⁴
- They report statistics and outcomes at an annual educational conference for referring physicians.
- These statistics and outcomes are not presented to Hospital Quality Review Committee for their review and comments.
- Important patient care issues were not studied.
- There were no formal protocols for the studies.
- These important studies could not be reviewed by the Department of Surgery or forwarded to the Medical Executive Committee or Governing Board for their oversight and review.

²² We have no evidence that Centers for Medicare and Medicaid Services sent a copy of its warning letter to its payment contractors, National Heritage Insurance Company and its fiscal intermediary (FI) which paid the physicians and Redding Medical Center respectively, or to commercial insurance companies that provide Medicare secondary insurance payments. The medical review departments of all these payers rely on peer review to guarantee that hospital based medical care is within accepted standards of care. For example, neither Centers for Medicare and Medicaid Services Contractor Medical Director nor a commercial insurance company medical director would suspect a cardiac catheterization report is falsely reported or that a surgeon would accept a false report and operate anyway.

Centers for Medicare and Medicaid Services could have asked **National Heritage Insurance Company** to review Medicare payments made to Redding Medical Center physicians for cardiac services. By knowing that the quality controls of hospital peer review were not in place, suspicious National Heritage Insurance Company reviewers could have reviewed the medical works-ups to determine the necessity for the catheterization procedures. The Centers for Medicare and Medicaid Services contractors are paid to enforce Medicare laws of medical necessity. Centers for Medicare and Medicaid Services left them out of information loop.

We asked the Hospital Quality Improvement Contractor, which is now called Lumetra, whether its medical review staff was aware of problems with Dr. Moon and Dr. Realyvasquez. Information from Lumetra is not available under the Freedom of Information Act, even though it is a Medicare Contractor.

²³ *Health Care Financing Administration* -2567 Page 1 of 9, 10/28/99

²⁴ Objective peer review is difficult with only two physicians and impossible when both are in the same group and one is employed by the other. Outside experts would have had to provide the peer review, which eventually the FBI arranged.

To correct the element of the conditional violation, Redding Medical Center proposed to provide:

- Monthly peer review,
- Semi-annual review of the cardiovascular surgery statistics and outcomes measures to be reported to the Surgical Care Committee,
- The Surgical Care Committee would regularly review Cardiovascular Performance improvement studies and minutes with respect to study designs, physician advisor and expected time for completion.²⁵
- The Surgical Care Committee membership was expanded to include a surgeon member of the cardiovascular team and the nursing director of the Cardiovascular ICU, to facilitate regular, ongoing communication of any other Cardiovascular Service quality improvement activities.²⁶

The Responsible Positions for the corrective action plan prompted by the re-survey were the Director of Outcomes Management and Chairman of Quality Committee.

Although by now Redding Medical Center complied with most of the Condition of Participation requirements, one critical element, peer review for cardiac services (Element 54), remained violated. Despite its violation California Department of Health Services Licensing and Certification Division recommended to Centers for Medicare and Medicaid Services that Redding Medical Center sufficiently complied with federal requirements and had full capacity to provide adequate care to its patients. California Department of Health Services Licensing and Certification Division recommended, and Centers for Medicare and Medicaid Services agreed that violation of this single element of the Condition of Participation was not sufficient to cause Centers for Medicare and Medicaid Services to withhold Redding Medical Center's provider status, even though the violation sheltered Dr. Moon and Dr. Realyvasquez from peer review. Dr. Moon and Dr. Realyvasquez remained chiefs of their departments, with power over their own peer review which allowed their negligence to continue.

We asked California Department of Health Services Licensing and Certification Division personnel in the Chico office of Licensing and Certification why California Department of Health Services Licensing and Certification Division²⁷ removed Redding Medical Center from its survey revisit list despite its October 1999 finding that element 054 remained violated. California Department of Health Services Licensing and Certification

²⁵ Although the Surgical care committee was to oversee cardiac surgery, this never happened. Dr. Realyvasquez remained in charge of self-administered peer review.

²⁶ Note that none of these corrective activities would assure that the medical cases of Dr. Moon and Dr. Realyvasquez would be reviewed independently, that the imaging services Dr. Moon performed were medically indicated, or that the images would be checked by outside experts to validate Dr. Moon's reports. In retrospect we can understand how these corrective measures could have cleverly been crafted by Redding Medical Center in order to avoid correcting the problem while giving the appearance of its intent to comply with the federal requirement (54). California Department of Health Services Licensing and Certification Division and Centers for Medicare and Medicaid Services may not have considered that the inadequate peer review could be deliberate in order to increase profits, notwithstanding that there was plenty of evidence of systematic over-treatment at Redding Medical Center.

²⁷ The Chico Office of Licensing and Certification is the office that performs the surveys. L&C is part of California Department of Health Services Licensing and Certification Division.

Division explained they do not have the resources to follow-up on every violation, and, based on their judgment, Redding Medical Center did not need additional inspections.

According to Centers for Medicare and Medicaid Services²⁸, a violation of an element of a Condition is not sufficient to rule the entire Condition is violated. Partial compliance is good enough. Because of Redding Medical Center's partial compliance a letter dated March 29, 2000 (on behalf of Mr. Wayne), Mr. Ron Ho rescinded the Center's requirement that California Department of Health Services Licensing and Certification Division continue to monitor Redding Medical Center. Thereafter, Centers for Medicare and Medicaid Services would follow the recommendations of the Joint Commission, which fully accredited Redding Medical Center. The Joint Commission accreditation verified to Centers for Medicare and Medicaid Services that Redding Medical Center fulfilled all the Medicare Condition of Participations. At this point, Redding Medical Center was off the hook.²⁹

In summary, beginning in 1993, Dr. Campbell and his colleagues identified two cases of substandard care by Dr. Moon and Dr. Realyvasquez and suspected many other cases. Redding Medical Center supported Dr. Moon and Dr. Realyvasquez and blocked complaining physicians. Concerned physicians believed if they took action to rectify this situation there would be retaliation against them by hospital administration and the culpable physicians, which could include character assassination as well as loss of directorship salaries, hospital service contracts, and patient referrals. Dr. Moon and Dr. Realyvasquez controlled and hospital administration interfered with peer review of cardiac services required by Redding Medical Center policies, State regulations, and Medicare Condition of Participation.

The four surveys in 1999, three by California Department of Health Services Licensing and Certification Division and one by Joint Commission and the Institute for Medical Quality, documented that beginning in 1997 (1) there was no peer review of cardiovascular services, (2) appropriate diagnosis and treatment was not assured, and (3) patient safety was not assured.³⁰ Nonetheless, the Joint Commission accredited Redding

²⁸ Captain Steven Chickering, MS, RN, Western Consortium Survey & Certification Officer, MS Region IX

²⁹ According to a California Department of Health Services Licensing and Certification Division official, when the Joint Commission accredits a hospital, under Joint Commission's deemed status, California Department of Health Services Licensing and Certification Division is prevented from going into the hospital as an agent of Centers for Medicare and Medicaid Services unless Centers for Medicare and Medicaid Services gives California Department of Health Services Licensing and Certification Division authorization to do so. California Department of Health Services Licensing and Certification Division can always perform a state survey looking for compliance with state laws and regulations, but in general those regulations are less specific and less directive than the Medicare Condition of Participation requirement for peer review. In the absence of a complaint, the Centers for Medicare and Medicaid Services will accept the Joint Commission accreditation as verification that the Medicare Condition of Participation is met.

³⁰ California Department of Health Services Licensing and Certification Division may not have known the cardiac care was negligent, but they knew peer review was absent and therefore the hospital could not assure that cardiac care was safe or appropriate. California Department of Health Services Licensing and Certification Division could have checked the claims that these physicians reported to Medicare and Medi-Cal. Several physicians had complained about negligent care to Redding Medical Center CEOs and to the

Medical Center. Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division accepted Redding Medical Center because its violation was only one element of a Medicare Condition of Participation.

California Department of Health Services Licensing and Certification Division and Centers for Medicare and Medicaid Services may have known, and reasonably should have known that the cardiac services were principal income generators for Redding Medical Center, and that the income could have motivated deliberate non-compliance.³¹ California Department of Health Services Licensing and Certification Division did not solicit anonymous comments from Redding Medical Center medical staff,³² nor did it notify the commercial insurance payers or the public that Redding Medical Center could not guarantee patient safety. Centers for Medicare and Medicaid Services did not share its information with its contractors which review Medicare provider claims and quality. The Joint Commission and the Institute for Medical Quality findings remained confidential from the people and the government.

Most likely peer review by Stanford doctors, as promised in the Plan of Correction of June 1999 would have caused the review of patient records, the cardiac catheterization images, and the Intravascular Ultrasound images performed by Dr. Moon. Stanford physicians would have discovered Dr. Moon's patient work-ups were negligent, his image interpretations wrong, and his referrals to Dr. Realyvasquez inappropriate. They would have discovered Dr. Realyvasquez operated on healthy patients without bothering to verify they needed surgery, and some of the patients died from the unnecessary procedures.³³

Dr. Moon, Dr. Realyvasquez, the Redding Medical Center administrators, and the medical staff leaders they controlled, outmaneuvered California Department of Health Services Licensing and Certification Division, Centers for Medicare and Medicaid

Medical Board of California, demanding peer review and investigations respectively. California Department of Health Services Licensing and Certification Division could have solicited comments from all the physicians on the medical staff, inviting them to report information anonymously. The California Department of Health Services Licensing and Certification Division and the Joint Commission independently validated that peer review was not being done. The Medical Board of California had reason to suspect negligence, but neither California Department of Health Services Licensing nor Certification Division nor Centers for Medicare and Medicaid Services checked with the Medical Board of California. The public not only knew nothing but the Joint Commission mislead them to believe Redding Medical Center provided safe care when Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division found that patient safety could not be assured.

³¹ The Medicare B Centers for Medicare and Medicaid Services contractor from 1997 to 2008.

³² Had a physician complained to a Joint Commission surveyor or California Department of Health Services Licensing and Certification Division about Dr. Moon or Dr. Realyvasquez in 1999, neither the Joint Commission nor California Department of Health Services Licensing and Certification Division offered protections from hospital retaliation against a physician whistleblower. In 2006, both the State of California (AB632) and the Joint Commission now protect physician whistleblowers from hospital retaliation.

³³ Retrospectively, the information provided by the Medical Board of California when it revoked Dr. Moon's medical license in 2007, confirms that if the Stanford plan of outside peer review had been accomplished, the Redding Medical Center disaster most likely would have been detected stopped in 1999.

Services, the Joint Commission, concerned Redding Medical Center doctors, the Medical Board of California, Medicare payment and quality assurance contractors, and patients until the FBI raid.³⁴ Redding Medical Center remained a huge money maker for Tenet. Dr. Moon and Dr. Realyvasquez continued to profit substantially. Over the next three years, hundreds more patients were damaged.

Period 3: REDDING MEDICAL CENTER 2000-2002: PHYSICIAN EFFORTS TO STOP NEGLIGENT CARE AT RMC

Between 2000 and 2002, the Joint Commission, California Department of Health Services Licensing and Certification Division, and Centers for Medicare and Medicaid Services all reported that Redding Medical Center was in good standing. However, the medical staff remained concerned about the absence of peer review of the cardiac services at Redding Medical Center. In the summer of 2000, Redding Medical Center appointed trauma surgeon³⁵ Dr. Ian Grady as director of the Quality Committee. Its jurisdiction included oversight of peer view effectiveness, but did not conduct it. Its members came from both the administration and the medical staff. The Quality Committee reported to the CEO, the Board of Directors and the Medical Executive Committee.

The Redding Medical Center administration, with medical staff advice, assigned various tasks to the Quality Committee such as to find ways to reduce turn around time in operating rooms. In 2000, Dr. Grady asked Ms. Jan Chicoine, the Redding Medical Center employee in charge of quality review, to submit documentation to prove the Redding Medical Center plan of correction promised to the California Department of Health Services Licensing and Certification Division in 1999 was underway, including peer review of cardiac services. Chicoine said she would request the documentation.

During the weeks that followed, Dr. Grady repeatedly requested the documentation but never received it. Instead, Chicoine sent the Quality Committee quarterly statistics on patient care outcomes, but withheld detailed information on specific complications and corrective actions, indications for cardiac surgery, and second opinions of cardiac imaging studies. Chicoine explained that these details were protected and could be not be shared with the Committee according to California Evidence Code §1157 and Business and Professions Code §§805-809.³⁶ Chicoine reassured Dr. Grady that specific peer review reports would be forwarded to the departments of medicine and surgery as needed, where the work of reviewers was protected from outside discovery by lawyers. If there were a delay in review by the departments, then it would come to the Quality Committee for further action. She reassured Dr. Grady this process was sufficient to comply with the Redding Medical Center Plan of Correction promised to California

³⁴ These efforts are one reason we believe current laws are not adequate to protect patients. The well-intended physicians at Redding Medical Center knew something was wrong but remained ineffective.

³⁵ One of the authors of this report

³⁶ Interview with Jan Chicoine, 11/2007

Department of Health Services Licensing and Certification Division and Centers for Medicare and Medicaid Services in response to their deficiency citations.³⁷

Chicoine explained that:

- Cardiac services had no complications that required peer-review.
- Redding Medical Center had established its California Heart Institute. This Institute did its own peer review using outside consultants.
- Redding Medical Center's cardiac service was so advanced that the Redding Medical Center medical staff would not have the knowledge or experience to review the cases.³⁸
- Because peer review was being conducted by outside reviewers, nothing needed to be forwarded to the Quality Committee or the respective departments for action.³⁹

The Quality Committee never received the documentation necessary to verify whether peer review in the cardiac and cardiovascular departments was adequate.⁴⁰

Retrospectively, it appears to the Committee chairman⁴¹ that Redding Medical Center never intended to share medical records with the Quality Committee under any circumstances.⁴²

On February 21, 2001, Dr. Frank Sebat⁴³, the director of critical care services and a member of the Medical Executive Committee and governing board at Redding Medical Center, complained about the ineffectiveness of physician peer review in a letter to CEO Hal Chilton; Chief of Staff; Dr. Gil Fitz; Dr. Ian Grady, Chairman of the Quality

³⁷ Redding Medical Center had cleverly designed its Plan of Correction to keep its rainmakers free from peer review oversight. Retrospectively, we believe the California Department of Health Services Licensing and Certification Division was fooled into accepting a Plan of Correction that would protect Redding Medical Center's cash flow and not protect its patients. We will return to this point in our recommendations.

³⁸ Chicoine's opinion was wrong. Moreover, she was not professionally trained enough to know what physicians can reasonably be expected to know about cardiac work-ups and imaging. The pre-procedure work-up of suspected cardiac patients by Dr. Moon was negligent, which any properly trained internist or family doctor would recognize. Any reasonable cardiologist would question whether intravascular ultrasound findings could support a coronary artery bypass graft surgery on a patient with normal coronary catheterization findings, and would solicit an opinion from a non-conflicted, independent outside intravascular ultrasound expert and expect to find support within the scientific literature.

³⁹ If any outside reviewers reviewed Dr. Moon's work, Redding Medical Center controlled the findings.

⁴⁰ The quality committee was not a peer review committee and its members may not have been subject the California Evidence code §1157 protections. These protections apply to peer review panel members in case of legal retaliation by physicians who are reviewed. The Quality Committee might have waived these protections to access the medical case files, but Redding Medical Center did not offer this option to the Committee members. Accordingly, the Quality Committee did not have the power to correct the absence of peer review which violated 42 CFR 481.21. The only physicians that could know whether the Plan of Correction was performed were Dr. Moon and Dr. Realyvasquez. The Plan of Correction was doomed to fail.

⁴¹ Dr. Ian Grady is a co-author of this report.

⁴² The ineffective oversight of the Quality Committee supports our recommendation that Congress allow Centers for Medicare and Medicaid Services to cut off payment for groups of services (e.g. elective cardiac procedures when COP are not met in that service) in order to force a hospital to comply with federal requirements.

⁴³ One of the authors.

Committee; Dr. Realyvasquez, a Board Member; Doug Treadway, Chairman of the Redding Medical Center Board of Directors, and Jan Chicoine, Redding Medical Center administrative head of quality assurance.

Dr. Sebat wrote:

“The peer review process at Redding Medical Center has fallen below reasonable expectations. This is a result of the following:

- *The inconsistent structure and guidance which results in cases of malfeasance not being identified.*
- *The chart seldom effectively documents the malfeasance.*
- *Multiple sources of information (such as incident reports or interviews with witnesses) are not considered during the peer review process.*
- *Reviewers are sometimes reluctant to be candid regarding their review.*
- *Ineffective action or inaction once the peer review has been completed.*
- *The reporting process to the medical committee structure and ultimately to the Board of Directors of the hospital is not structured to allow effective oversight.*

The mind set among the medical staff is that peer review is ineffective and therefore physicians do not wish to expend energy or risk alienation of colleagues for little, if any, detectable benefit.”

Dr. Sebat made several recommendations for process improvement including:

“For the medical staff’s Process Improvement Team to review the Peer Review Process and restructure it to cure the deficiencies that cause it to be ineffective.”

In response, a Hospital Board subcommittee was established to review and improve the peer review process. During its first three monthly meetings this hospital board subcommittee identified relevant problems, but did not have the time needed to develop a plan of correction. After its third meeting, in 2001, Mr. Dennis Brown, regional vice-president of Tenet Healthcare and a member of the Board of Directors of Redding Medical Center unilaterally disbanded the subcommittee. Brown simply told the Board that the subcommittee’s work was done. At the next Board meeting, several subcommittee members of the Board objected, asserting their work was not done.

Subsequently, the medical staff established its subcommittee to continue to evaluate and improve its peer review process. Its committee chair was Dr. Fitz, Chief of Staff. However, Dr. Charles Springfield, vice-chief of staff typically set the tone and agenda of the meeting. Dr. Springfield was head of the emergency department whose physicians worked at the hospital under an independent contractor agreement. Redding Medical Center paid Dr. Springfield a salary to serve as department director. He was also a member of the Governing Board of Redding Medical Center. Other subcommittee members included Dr. Daniel Alcala, an internist and Chief of Medicine, and Dr. Maya Sandberg, a vascular surgeon and principal assistant to Dr. Realyvasquez. The

subcommittee met intermittently over a six-month period then tapered off. The subcommittee eventually disbanded accomplishing nothing.

In the spring of 2002, Dr. Frank Sebat addressed many quality concerns about Dr. Tom Russ that were before the Medical Executive Committee and persuaded it to take action. Dr. Russ worked in Dr. Moon's group. The Medical Executive Committee temporarily suspended Dr. Russ from the medical staff. In response, the Redding Medical Center administration retaliated against Dr. Sebat. Within weeks, Redding Medical Center notified Dr. Sebat by certified letter that his ICU director contract was to be immediately renegotiated. Dr. Springfield, speaking for Redding Medical Center, told Dr. Sebat he would be permitted to keep his ICU director contract if he resigned from the Medical Executive Committee and the Governing Board. He was to focus on ICU matters only, notwithstanding that his contract required his participation in medical staff committees and peer review.

In 2001, the chief of anesthesia, Dr. Robert Hanson, asked Redding Medical Center administration and acting Chief of Staff, Dr. Springfield, to discipline Dr. Realyvasquez for commanding an anesthesiologist to leave a patient during open-heart surgery thereby endangering the patient. In response the hospital CEO threatened to terminate part of the contract with Dr. Hanson's group and arrange separately for cardiac anesthesia.

PERIOD 4: 2002 SURVEYS JUST BEFORE THE FBI RAID

The Joint Commission surveyed Redding Medical Center beginning July, 2002. The Joint Commission continued the accreditation of Redding Medical Center. We do not know about the findings. Joint Commission accredited Redding Medical Center which Centers for Medicare and Medicaid Services accepted as verification that Redding Medical Center complied with Medicare Condition of Participation. In the absence of a complaint, Centers for Medicare and Medicaid Services took no action.⁴⁴

In 2002 California Department of Health Services Licensing and Certification Division resurveyed Redding Medical Center on a routine basis. California Department of Health Services Licensing and Certification Division reviewed the Medical Care Committee meeting minutes of 8/28/02. The minutes revealed peer review of six cardiac catheter cases with complications and two patient complaints. The six complications were not related to the angiogram findings so the angiogram and Intravascular ultrasound images were not reviewed. The Committee did not validate the need for the catheterizations, the need for invasive therapy, such as intra-coronary stent placement, or the need for any surgery that followed. The two patient complaints involved two angiographic procedures, one with intravascular ultrasound. Complaint No.1⁴⁵ alleged that the angiogram image did not support the cardiologist's conclusions that surgery was necessary. The State survey reports that the minutes of the review showed the cardiac angiogram and intravascular ultrasound were reviewed by a second Redding Medical Center cardiologist. The second

⁴⁴ Under its deemed status, when the Joint Commission accredits a hospital, absent another complaint, Centers for Medicare and Medicaid Services considers the hospital compliant with its Conditions of Participation.

⁴⁵ We believe this complaint was filed by Father Corapi, the first patient to go to the FBI.

cardiologist reviewer agreed with the first cardiologist who did the procedure. The studies showed significant coronary artery disease warranting surgical intervention.

However, we contacted the cardiologist who reviewed the first complaint⁴⁶. He told us the coronary angiograms did **not** show critical disease and the Intravascular ultrasound could not be interpreted due to inappropriate setting of the gain controls on the ultrasound equipment. Dr. Moon set the gain controls to 60 when the manufacturer recommended 52. The higher gain setting produced artifact which Dr. Moon used to interpret as disease. The cardiologist reviewer found that Dr. Moon's work-up did not support his recommendation for surgery. Therefore, the peer review minutes composed by Redding Medical Center did not fully reflect the reports of the reviewer and hid Dr. Moon's error. When California Department of Health Services Licensing and Certification Division reviewed the minutes, the peer review appeared adequate when in fact it was not. Information after the FBI raid substantiates that Dr. Moon repeatedly misinterpreted intravascular ultrasound, ignored relatively normal coronary angiograms, and recommended surgery.

The 2002, California Department of Health Services Licensing and Certification Division survey reports that following its 1999 second re-survey, Redding Medical Center attempted to re-institute peer review in the cardiovascular service, but was unsuccessful because *"the surgeons and the cardiologists were too busy... to attend the meetings that did the quality assurance peer review of cardiac surgery and cardiology."*⁴⁷

The minimal peer review performed did not comply with California Department of Health Services Licensing and Certification Division requirements. To correct its violation, Redding Medical Center proposed to ensure that a sampling of cardiac films, angiograms and other cardiac studies would be reviewed retrospectively on a quarterly basis by a second cardiologist not affiliated with the first cardiologist.⁴⁸ The medical staff would be responsible for determining the sample. California Department of Health Services Licensing and Certification Division accepted Redding Medical Center's plan of correction and did not report the peer review deficiency to Centers for Medicare and Medicaid Services.

Therefore, after ten years and four surveys by California Department of Health Services Licensing and Certification Division and two by Joint Commission/the Institute for Medical Quality, Dr. Moon underwent extremely limited and ineffective peer review based on patient complaints and the peer review remained inadequate.⁴⁹

⁴⁶ Dr. Vimal Nanavati.

⁴⁷ Deposition testimony of Dr. Anthony Way, Chief Medical officer of Licensing and Certification, Department of Health Services, State of California.

⁴⁸ Redding Medical Center promised the same review in 1999. Redding Medical Center had no independent cardiologist familiar with intravascular ultrasound who could provide competent peer review.

⁴⁹ Note that California Department of Health Services Licensing and Certification Division had decided in 1999 that the peer review violation of an element of a Condition of Participation was insufficient reason to keep tabs on Redding Medical Center.

OTHER REVIEWS

Seven complaints by physicians, as previously referred to, were filed with the Medical Board of California⁵⁰ against Dr. Moon and Dr. Realyvasquez prior to October, 2002. In response, the Medical Board of California asked each patient involved to authorize a review of their confidential medical records by State medical experts. The patients either denied the requests or failed to respond. As a result, the Medical Board of California did not pursue any of these complaints. It was not until after the federal raid that the Medical Board of California accused Dr. Moon and Dr. Realyvasquez of negligence, citing the evidence the FBI developed to obtain its search warrant. The Medical Board of California had no evidence of its own. Five years after the FBI raid and its completion of extensive investigation and hearings the Medical Board of California revoked Dr. Moon's license to practice medicine in 2007.

The Medicare Carrier, National Heritage Insurance Company, a subsidiary of Electronic Data Systems, Inc. audited Dr. Moon services around 1998 and required him to reimburse about \$2,000.00 which he did without objection. In 2000, National Heritage Insurance Company paid Dr. Moon more than it paid any other cardiologist in northern California, over \$1 million annually just for Medicare patients. The carrier audited Dr. Moon a second time around 2001, but found Dr. Moon has not been overpaid. Thus, after two reviews, National Heritage Insurance Company's medical experts did not suspect that Dr. Moon was frequently performing unnecessary procedures. National Heritage Insurance Company reviewers relied solely on Dr. Moon's written reports and his medical files to determine whether the procedures were medically necessary. They did not review the preoperative work-up which should have included one or more of the following: patient history consistent with coronary artery disease including chest pain with exertion, ischemic finding on electrocardiogram, positive cardiac enzymes, positive stress or echocardiogram. In addition, his angiographic and ultrasound images were not reviewed to determine whether they were consistent with his written reports. This kind of analysis was the only way to know whether the procedures Dr. Moon performed were medically indicated. As a result, the carrier's medical review department did not stop payments to Dr. Moon and reported nothing to its Medicare benefit integrity division for possible referral to federal authorities for a criminal investigation or to the Medical Board of California for suspected medical negligence.

Centers for Medicare and Medicaid Services did not inform Dr. Gerald Rogan,⁵¹ National Heritage Insurance Company's chief medical officer that the medical staff at Redding Medical Center did not perform peer review of cardiac services. Following the FBI raid, a physician in Chico reported another case of Dr. Moon's negligence to Dr. Rogan. The patient, who resided in a small town north of Chico, had unnecessary surgery by Dr. Realyvasquez after referral by Dr. Moon upon finding a normal coronary arteriogram.⁵²

⁵⁰ Personal communication from Office of the Inspector General agent to Rogan.

⁵¹ One of the authors of this report.

⁵² The patient was treated by a local cardiologist after the coronary artery bypass graft surgery. The cardiologist asked for the films and found they were normal. The cardiologist admitted to Dr. Rogan she did not know what to do about the case and was afraid to report it to government authorities.

At least two private insurers were concerned about services at Redding Medical Center. Like National Heritage Insurance Company, one of these insurers did not routinely review pre-test work-ups to validate the need for a catheterization or review the images themselves to be sure the interpretations that prompted surgery were correct. Another insurer refused to sell managed care health insurance in the Redding market because of the high cost of medical care in the area, driven by the Redding Medical Center cardiac program.

PERIOD 5: OCTOBER 22, 2002

The FBI raid followed a three-month investigation set in motion by Dr. Moon's patient, Fr. John Corapi. After getting second, third, fourth and fifth opinions, all of which disagreed with a diagnosis and surgery recommendation by Dr. Moon, Fr. Corapi got in touch with the FBI. Bolstered by interviews with Redding Medical Center medical staff, other patients of Dr. Moon and Dr. Realyvasquez, a handful of their colleagues, Dr. Rogan, and outside cardiologists as far away as the Cleveland Clinic, the FBI produced a 67-page affidavit that led to the issuance of a search warrant authorizing the raid. The affidavit contained a description of Dr. Moon's interaction with the patients. Dr. Moon bullied the patients and scared them. Dr. Moon would consistently tell patients, many of whom had ambiguous symptoms and no history of coronary disease that he needed to perform an angiogram to determine whether the patient required invasive treatment.⁵³

If the angiogram failed to document treatable disease or, as frequently was the case with Dr. Moon, was unreadable, he would perform an intravascular ultrasound which at the time was quite new and unfamiliar to many cardiologists. By improperly setting the gain on the ultrasound too high, Dr. Moon guaranteed the appearance (but not the reality) of significant arterial blockages. Dr. Moon would then lean over the supine patient and tell him in dire tones that without immediate bypass surgery he would die. In such a stressful situation, few Redding Medical Center patients were sufficiently confident, rational, or sophisticated to ask for a second opinion. For the few who did, Dr. Moon typically referred the patient to Dr. Realyvasquez, who would then confirm Dr. Moon's diagnosis. Dr. Realyvasquez would rely on Dr. Moon's recommendation and perform surgery.⁵⁴

After the federal raid in 2002 the California Medical Board sought a restraining order against Dr. Moon and Dr. Realyvasquez based on the following findings:

- *“Both Drs. Moon and Realyvasquez have fraudulently misrepresented the findings of tests to induce and/or to scare patients into having unnecessary surgeries or interventions.*

⁵³ An angiogram is a diagnostic test that involves making an incision in the patient's groin accessing the artery and threading a catheter into the coronary circulation, injecting dye, and taking X-ray pictures of the arteries.

⁵⁴ The technique worked well for 10 years because (1) formal peer review was thwarted, (2) physicians were intimidated to keep quiet, (3) Redding Medical Center could promise compliance to California Department of Health Services Licensing and Certification Division and then ignore its promise, (4) Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division would not impose any penalties for lack of compliance.

- *The pattern of medical practice and judgment demonstrated by [Dr. Moon and Dr. Realyvasquez] clearly demonstrates that they are not presently fit to practice medicine. At best, respondents' conduct in this respect can be viewed as incompetent and/or grossly negligent as well as dishonest and corrupt.*
- *Respondents have engaged in conduct with their patients in which invasive coronary tests were routinely performed without a medical basis therefore, unnecessary surgical procedures, including coronary bypass operations were performed with significant risk and/or harm to the patient(s), and Respondents misled, lied to or attempted to frighten patients into consenting to invasive coronary surgical procedures, at significant risk to the patient and with significant potential financial gain to respondents”⁵⁵*

CASE REVIEWS: A WIDESPREAD AND ONGOING PROBLEM

We have shown that the negligence at Redding Medical Center continued for at least 10 years because peer-review was inadequate, government enforcers knew it, and Redding Medical Center got away with it until law enforcement intervened. We will now document six similar cases across the country where long-term, uncorrected negligence at hospitals was stopped by law enforcement. We postulate each of these cases could not happen if medical staff peer review had been properly done.

MERCY HOSPITAL (SACRAMENTO): In 1974, Judge B. Abbott Goldberg held an orthopedic surgeon named John Nork responsible for negligent surgery on a 32-year-old grocery clerk named Albert Gonzalez. During the trial Dr. Nork admitted to additional negligent and unnecessary operations. In a 196-page memorandum of decision, the judge concluded that at least 50 more surgeries might have been “*unnecessary, bungled or both.*” Throughout his opinion, Judge Goldberg made reference to multiple occasions when Dr. Nork’s colleagues could have and should have blown the whistle. The judge also held the hospital responsible for the conduct of attending physicians, which was a legal precedent. In the wake of the trial, Dr. Nork was facing at least 33 malpractice suits, 27 of which also named Mercy Hospital. Just weeks before Judge Goldberg’s decision, Dr. Samuel R. Sherman, a former California Medical Association president, had said that problems caused by physician negligence and incompetence exist “*almost everywhere in America, true, but no longer in California.*” The chairman of the Select Committee on Medical Malpractice of the California Assembly commented subsequently: “*That the facts about Dr. Nork only came to light after years of costly malpractice litigation demonstrates that our methods for detecting and correcting medical malpractice leave much to be desired.*” The chairman was Henry Waxman.⁵⁶

EDGEWATER: For six years ending in 2001 physicians, administrators and management company executives at Edgewater Medical Center in Chicago conspired to defraud

⁵⁵ Medical Board of California vs. Fidel Realyvasquez, M.D., and Chae Hyun Moon, M.D., Memorandum of Points and Authorities in Support of Petition for Temporary Restraining Order; Superior Court of California in and for the County of Shasta; November 6, 2002.

⁵⁶ Peer Review in 1974, *How Well Does Medicine Police Itself? Medical World News*, March 15, 1974, pp 62-72.

Medicare of tens of millions of dollars in a scheme that would have been impossible to implement had there been effective peer review and oversight. Dr. Andrew Cubria, a cardiologist, admitted performing unnecessary angioplasties and angiograms on more than 750 patients, two of whom died as a result of these unnecessary procedures. Dr. Cubria was sentenced to 151 months in prison and ordered to pay \$14,362,499 in restitution. Dr. Sheshiqiri Rao Vavilikolanu admitted that he unnecessarily hospitalized 900 patients. He was sentenced to 35 months in prison and ordered to pay \$6 million in restitution. Dr. Kumar Kaliana admitted receiving kickbacks in return for admitting patients and arranging cash payments to family members and others for recruiting patients who did not need hospitalization. He was sentenced to 16 months in prison and ordered to pay \$1,156,000 in restitution. Dr. Ravi Barnabas admitted funneling kickbacks to Drs. Rao and Kaliana in exchange for admitting patients to Edgewater. He was sentenced to 52 months in prison and ordered to pay \$100,000 in restitution. Roger Ehmen, an Edgewater vice president, admitted participating in schemes to pay kickbacks to recruit and hospitalize patients unnecessarily. He was sentenced to 78 months in prison and ordered to pay restitution of \$5 million. Two management companies were ordered to pay \$2.9 million for criminal fraud.⁵⁷

WESTERN MEDICAL CENTER: In March 2005, ten years after Dr. Israel Chambi, a neurosurgeon, was dismissed by the University of California at Irvine for incompetence, the Medical Board of California filed an accusation against him in a single case. According to the accusation, which has yet to be acted upon, Dr. Chambi “*committed gross negligence, repeated negligent acts and/or was incompetent during his care, treatment and management of patient F.H.*”⁵⁸ As a result of Dr. Chambi’s negligence, F.H., a star tennis player, who was 16 years old at the time, has suffered ever since from pain, numbness and weakness in her right arm. From 1995 when he was asked to leave U.C. (Irvine) until 2003, Dr. Chambi practiced at Western Medical Center in Santa Ana, CA, where he generated millions of dollars in income for the hospital and its owner, Tenet Healthcare. During his tenure at Western he was sued for malpractice 39 times before finally being suspended and moving on to Tustin Hospital Medical Center where he currently practices without restriction. In 2003 Charles Grassley (R-Iowa), chairman of the Senate Finance Committee, sought information about Dr. Chambi in the context of his interest in “*the type of peer review Tenet is doing or not doing and whether the company is prohibiting the peer review of these doctors with the goal of keeping them in place and keeping their high billing practices for the company.*”⁵⁹

UNIVERSITY OF KANSAS MEDICAL CENTER: Herbert A. Daniels, M.D., was found guilty in December of 2001 of 33 counts of healthcare fraud, seven counts of mail fraud and three counts of perjury dating back to 1986. Dr. Daniels was an ear, nose and throat specialist who performed surgery at the University of Kansas Medical Center, Bethany

⁵⁷ *Edgewater Medical Center Management Firms To Pay \$2.9 Million In Resolving Related Criminal and Civil Health Care Fraud Cases*, U.S. Department of Justice press release, January 15, 2003.

⁵⁸ Medical Board of California, Accusation against Israel Pedro Chambi Venero, March 29, 2005.

⁵⁹ Jill Gerber, spokeswoman for Grassley, quoted in *Western Medical Center Takes Action Against Doctor with Long History of Medical Suits*, Chris Knap, Bernard Wolfson, and William Heisel, The Orange County Register, September 12, 2003.

Medical Center and Providence Medical Center. According to the U.S. Attorney's office, Dr. Daniels convinced patients to undergo unnecessary surgery to fill his surgical schedule, resulting in bodily harm to at least one patient. He also billed for services that were not rendered or were not medically necessary and charged for more expensive services when a less-expensive procedure was performed. Dr. Daniels also was found guilty of creating false documents and giving false testimony. Dr. Daniels was sentenced to six years in prison and his medical license was revoked, but it took 15 years and the involvement of federal law enforcement agencies to stop him.⁶⁰

GARLAND COMMUNITY HOSPITAL: Dr. Bruce Hinkley, an orthopedic surgeon, tested positive for cocaine time and again over an 11-year period, yet with only a couple of brief interruptions he continued to perform complex back surgery. About 20 malpractice suits have been filed against him. After testing positive for cocaine in September 1988, the hospital in McAlester, OK, where he had been practicing, suspended him. Dr. Hinkley also had a Texas medical license. He moved to Dallas and continued to practice at suburban Garland Community Hospital. He considered returning to Oklahoma in 1992, but his license in that state had lapsed and his application for a renewal was denied. Garland knew of his record of drug abuse, but he was one of their biggest sources of revenue. The hospital took no action against him. It was not until 1999 that the Texas State Board of Medical Examiners finally suspended Dr. Hinkley's license and not until a year later that the board revoked it. In 2005, WFAA, a Dallas television station reported that Dr. Hinkley was practicing medicine without a license at a local clinic.⁶¹

NEW HANOVER REGIONAL MEDICAL CENTER: When Dr. Steven E. Olchowski was granted a license to practice medicine in North Carolina in 1995, he had a 17-year history of alcoholism and psychiatric problems. He joined a surgical practice in Wilmington and began doing bariatric surgery at New Hanover Regional Medical Center. Eventually he was performing about 15 operations a week and bringing in millions of dollars in revenue. There were problems, though. He was billing for a complicated, but thoroughly tested procedure that is considered the gold standard. He actually performed short-cut operations that were not appropriate and not covered by insurance companies. He is now facing about three dozen malpractice suits. Moreover, there is evidence that both hospital administrators and the State Medical Board knew of his negligence but failed to stop him. In 2001, for example, a surgical sales representative told a nurse that Dr. Olchowski was performing the short-cut surgery and, according to court records, the nurse told the hospital administrators. Patients also complained about getting the wrong surgery or botched surgery. In 2002, Dr. Olchowski was fired by his surgical practice for "*incompetence, negligence or misconduct.*" More than a year later, he resigned from the hospital. It took another two years before North Carolina revoked his license during

⁶⁰ Leawood Physician is Convicted of Fraud, Anne Lamoy, Kansas City Star, December 4, 2001; Dodge City.com,

⁶¹ Drug past, discipline didn't stop doctor State board took years to revoke license, Swanson, Doug J., Dallas Morning News, July 1, 2001. Do No Harm: The De-Licensing of former doctor Bruce Stanton Hinkley, NBC News Dateline, July 25, 2003. Texas Medical Board, Physician Profile, Public Verification/Physician Profile, Bruce Stanton Hinkley, M.D. Unlicensed doctor may be treating Dallas patients, Brett Shipp, WFAA-TV.

which time he was operating at a small hospital in Michigan and had changed his name from Olchowski to Hawkins. On March 15, 2006, his Michigan license was suspended.⁶²

THE NATIONAL PRACTITIONER'S DATA BANK

We have analyzed data from the Public Access files of the National Practitioner Data Bank regarding physician errors committed in a hospital setting. Under federal law, the Data Bank is a depository for all peer-review actions that prompt voluntary or involuntary restriction or removal of a physician's hospital privileges and for all malpractice settlements and awards. Peer review committees through the hospital administrative staff and licensing agencies report changes in privileges. Medical liability insurers report malpractice settlements and judgments.

Although the data bank has been in operation since 1992, only since January, 2004 is the data detailed enough to allow an analysis of hospital inpatient events. The nature of each report is described in the data bank, but the details are not available to the public. However, one can analyze the physician's role in the events based on the limited publicly available information.

We divided abstracted information in the National Practitioner Data Bank about adverse events into four categories: low, moderate, high, and indeterminate culpability. Culpability level refers to the physician's responsibility for the adverse event and its seriousness. A low culpability event is a simple error that occurs as a result of human fallibility and the imprecise nature of medical science. Low culpability does not comprise negligence. An example is a common bile duct injury during gallbladder removal. A medium or high culpability event results from a departure from the standard of care. An example of a moderate culpability event is when a physician on-call refuses to see a critically ill patient in a timely manner resulting in a bad outcome. An example of a high culpability event is an inebriated surgeon operating on a patient.

Low culpability events are best addressed through education, continuous improvements in medical technology and research to improve healthcare techniques. Physician peer-review is designed to correct all adverse events, but mainly focuses on moderate and high culpability events. When a physician undergoes peer review for a moderate or high culpability event, the action taken may or may not affect the physician's hospital privileges and therefore may or may not be reported to the National Practitioner Data Bank. There were 310,000 physician events (from 1990 to 2007) reported to the National Practitioner Data Bank with an annual rate of approximately 18,000. Of these events, seven to eight thousand are inpatient physician errors of which 50% are medium and high culpability events (Fig 2). Reports from malpractice awards are 8 times greater than reports from peer review. We are concerned that this 8:1 ratio may reflect under activity by hospital peer review. A more detailed analysis of the National Practitioner Data Bank specific cases which are not available to the public is warranted.

⁶² Despite Warning Signs, Surgeon Continued Job; Wronged Patients of Weight-Loss Surgery Looking For Answers, Starnewsonline.com, Cheryl Welch, Feb. 23, 2005. Suit Claims Conflict of Interest By State Board; Local Medical Case In Evidence, Starnewsonline, Ken Little, March 1 2007. State of Michigan, Department of Community Health, Verify a License/Registration.

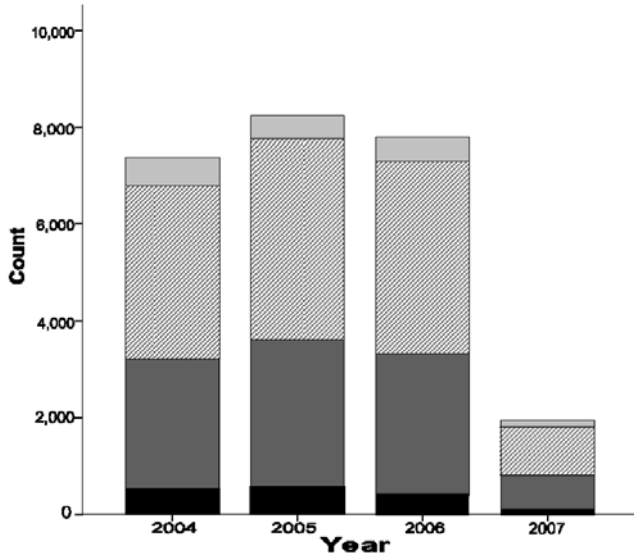


Figure 1: Physician Errors for Inpatient Care for 3 1/3 Years.

CULPABILITY ■ HIGH ■ MEDIUM ■ LOW ■ INDETERMINATE

This figure shows the total number of physician errors for inpatient care from January 2004 to April 2007. Moreover, the proportion of errors within each culpability category is relatively constant with approximately 50 per cent of the physician errors being moderate to high culpability.

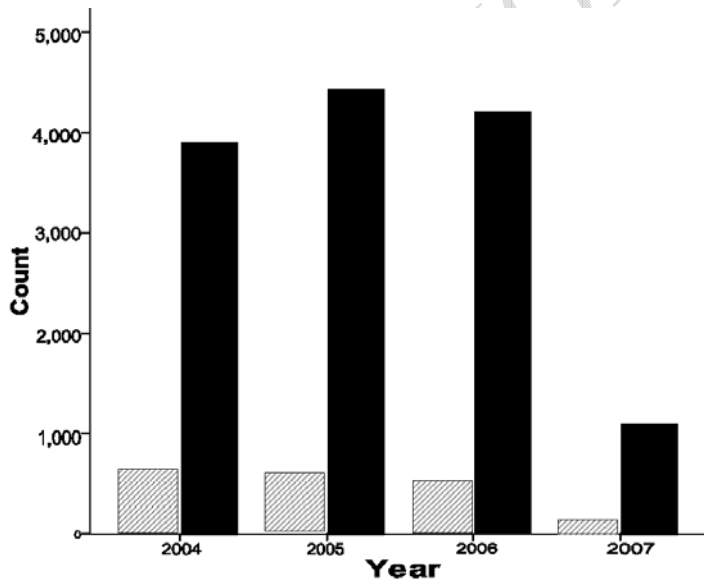


Figure 2: Physician-Related Moderate and High Culpability Events Reported Via Malpractice Judgments vs. Peer-Review Actions for Inpatients 2/2004-4/2007.

■ HOSPITAL PEER-REVIEW REPORTING ■ MALPRACTICE AWARDS REPORTING

Reporting by malpractice awards of greater than \$30,000 are 8 times more frequent than reporting by hospital peer review in moderate and high physician culpability events.

Peer review is protected from discovery, even when its results are reported to the Data Bank. One would suspect that peer review actions should exceed medical negligence settlements because (1) peer review is confidential and can occur without concomitant medical negligence litigation and (2) a settlement and malpractice award in excess of \$30,000 must be reported to the hospital medical staff in order to prompt peer review. Yet, we find the opposite with most moderate and high culpability physician errors reported by malpractice awards.

Likewise, in the seven examples of multiple cases of gross negligence over many years cited in this report, the frequency of lawsuits by damaged patients vastly exceed peer review reports. For example, there were many law-suits at Redding Medical Center but none of the cases of Dr. Moon and Dr. Realyvasquez were reviewed by peers in which action was taken by the medical staff prior to the FBI raid.

DISCUSSION AND REMEDIES

We present evidence from an analysis of the Redding Medical Center disaster which shows that peer review failed over many years damaging hundreds of patients. Incentives are aligned not to perform effective peer review. The reward of professional satisfaction from performing effective peer review is offset by punishment. Reviewers lose time from their practice without compensation. They lose patient referrals from the physicians they review. They are characterized by colleagues as being on a “*witch hunt*” or having ulterior motives such as to remove a competitor. If the physician reviewed is a rainmaker, the reviewer may lose grace with the hospital administration if poor quality is discovered.

The data suggests Redding Medical Center administration, Dr. Moon, Dr. Realyvasquez, and others deliberately thwarted peer review, in spite of the efforts of some physicians, California Department of Health Services Licensing and Certification Division, and Centers for Medicare and Medicaid Services to impose it. The absence of peer review between 1992 and 2002 violated Medicare Condition of Participation (42 CFR 482.21). Centers for Medicare and Medicaid Services, California Department of Health Services Licensing and Certification Division, and Joint Commission discovered the violation in 1999. Then, despite Redding Medical Center’s three promises to California Department of Health Services Licensing and Certification Division to correct the deficiency, its cardiac specialists, Dr. Moon and Dr. Realyvasquez said they were too busy to conduct it and their medical staff and administrators did not require them to do it. Nevertheless, Redding Medical Center kept Dr. Moon and Dr. Realyvasquez in charge of their respective hospital departments and the peer review processes for cardiac services.

Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division never enforced their peer requirements under federal and state laws despite their repeated findings that patient safety could not be assured. Moreover, following its current standards, Centers for Medicare and Medicaid Services accepted the absence of peer review as good enough to comply. California Department of Health Services Licensing and Certification Division also recommended that Centers for Medicare and Medicaid Services find that Redding Medical Center had sufficiently complied with the Medicare requirements. We conclude

that Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division standards for compliance are too low to assure patient safety.

Motivated by income generated by its rainmaker physicians, Redding Medical Center and Tenet preferred to support them rather than identify quality problems, including potential Medicare fraud. Government regulators rarely revoke a hospital's license or provider status and have no intermediate penalties to tip the balance toward peer review. For peer review to work, the penalties for not doing it must exceed the benefits.

When a hospital provides large salary and exclusivity guarantees and a highly paid department directorship requiring little or no work to a physician who is a rainmaker for the hospital, a conflict of interest is created. In this case it motivated Redding Medical Center to interfere with peer review and endanger patients.

It is unreasonable to allow a department director to retain the position when a Condition of Participation violation is discovered in that department and not corrected in a timely manner. If the deficiency is not corrected on a prompt re-survey, Centers for Medicare and Medicaid Services should suspend payment to physicians and the hospital for elective services provided by that department and demand the hospital remove the department director. Centers for Medicare and Medicaid Services must impose penalties severe enough to ensure that peer review is not profitable to suppress.

Regulatory enforcers allowed Redding Medical Center to get away with non-compliance, in part, because Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division have limited disciplinary tools, all of which are excessively blunt instruments: the removal of the hospital's provider status or the revocation of its license. Neither agency is willing to use this instrument. Therefore, government regulators have no effective power to enforce Quality assessment and performance improvement programs as required by State law. Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division have set the compliance bar too low. Both ignored the fact that Redding Medical Center could not assure patient safety.

We have discussed this situation with State and Federal authorities. The individuals we interviewed are frustrated by their lack of power. Without explanation, they defended their position that the violation of an element of a Condition does not justify a finding that the Condition as a whole is violated. Obviously, the patients who were damaged would disagree with their low standard.

In the other cases reported throughout the country, we suspect that peer review was not done based on circumstantial evidence: (1) many patients were damaged, (2) the negligence continued for years, and (3) law enforcement was involved. The National Practitioner Data Bank data also supports our judgment that peer review is frequently inadequate or not done in a number of hospitals.

We have proposed and the officials we interviewed agree that Congress must provide them with the authority to impose lesser (intermediate) penalties such as denial of payment for elective procedures in the service that is deficient. Intermediate penalties (sanctions) may be imposed upon clinical laboratories under Clinical Laboratory Improvement Act⁶³, upon nursing homes, independent diagnostic testing facilities, and physicians under various regulations, and under Medicare Modernization Act upon Durable Medical Equipment, Prosthetics, Orthotics, and Supply providers. Congress should enact laws to provide intermediate penalties on hospitals for violations of Medicare Conditions of Participation as it has done for other providers.

Congress should also set a higher standard for Condition of Participation compliance. Violation of any element that requires peer review should warrant violation of the Condition as a whole.

Congress should give Centers for Medicare and Medicaid Services the authority to instruct its Contractors to conduct detailed audits when a peer review deficiency is discovered. The Part B Contractor or a Recovery Audit Contractor should audit the physician members of the department, starting with the high billers. Diagnostic studies that are read by treating physicians who use their interpretations to justify additional procedures should be reviewed by outside experts and compared to the written reports. The medical indications for procedures and surgery should be reviewed. The physician who performs the procedure should independently verify that the surgery or procedure is medically necessary. The Quality Improvement Organization Contractor to Centers for Medicare and Medicaid Services should select hospital case samples of high volume services to review for medical necessity starting with any cases the State discovers were not reviewed as required.

Congress should provide the funds for these activities over a multi-year program so the contractors can develop the personnel and infrastructure necessary to accomplish their task.

At Redding Medical Center, Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division officials may not have known that unnecessary services were being performed, although the *Dartmouth Health Atlas* and National Heritage Insurance Company data at the time suggested this conclusion. The surveyors may not have suspected Redding Medical Center was actively suppressing peer review in order to protect its rainmaker physicians and the profits they generated for Tenet. Therefore, in order to improve the ability to detect sustained medical negligence, there should be improved communication and cooperation among oversight agencies. For example, the State Medical Board should be contacted to discover if quality complaints have been filed. Centers for Medicare and Medicaid Services should put in place a system at the hospital to solicit anonymous comments from its medical staff. Conditional violations, including *Elements of Those Conditions* should be posted in the professional staff lounge citing the deficiency and listing a phone number to report adverse events anonymously. Centers for Medicare and Medicaid Services should

⁶³ The Clinical Laboratory Improvement Act of 1988.

consider that inadequate peer review might be a deliberate attempt to cover up repetitive negligence.

Redding Medical Center's ongoing history of uncorrected violations never threatened its accredited status.⁶⁴ The Joint Commission accreditation gave credibility to Redding Medical Center so that it could mislead patients to conclude they were safe when, in fact, they were damaged. The Joint Commission accredited Redding Medical Center when it, the Institute for Medical Quality, Centers for Medicare and Medicaid Services, and California Department of Health Services Licensing and Certification Division knew Redding Medical Center could not assure patient safety. When Centers for Medicare and Medicaid Services and California Department of Health Services Licensing and Certification Division stopped their enforcement attempts, the Joint Commission was allowed to continue as Centers for Medicare and Medicaid Services survey agent even though none of its records are publicly available. Only the FBI brought in the outside experts necessary to perform the missing peer review.

The Joint Commission accredits approximately 90 per cent of the hospitals in the United States. A 2004 report by the General Accounting Office documents that the Joint Commission accreditation findings routinely under-reports deficiencies compared with State surveys.

“Centers for Medicare and Medicaid Services validation surveys during that time period confirmed that JCAHO [Joint Commission] missed the majority of serious deficiencies found by state survey agencies.”⁶⁵

The Redding Medical Center disaster proves that the Joint Commission accreditation process did not work and that Joint Commission is not accountable to Centers for Medicare and Medicaid Services. In fact, the Joint Commission misled Centers for Medicare and Medicaid Services. It was California Department of Health Services Licensing and Certification Division, not Centers for Medicare and Medicaid Services MS that reported Redding Medical Center to Centers for Medicare and Medicaid Services. To correct this, the Joint Commission needs to be accountable. Congress should consider whether to transfer to Centers for Medicare and Medicaid Services the authority to confer deemed status on an accrediting organization, just as it does for labs, physicians, independent diagnostic testing facilities and Durable Medical Equipment, Prosthetics, orthotics and Supply providers. Several accrediting organizations should be encouraged to develop, compete for business, and be held accountable to accreditation

⁶⁴ Accreditation is voluntary and is supported by hospital user fees. When the Joint Commission accredits a hospital, it determines whether the hospital meets the Medicare conditions of participation. Congress has given this authority, called “deemed status” to Joint Commission. The Joint Commission may impose additional accreditation requirements, which may be more comprehensive than the Medicare Condition of Participation. The only way the Joint Commission can impose its will on a hospital is to threaten to revoke its accreditation. Accreditation reports are confidential and not available to the public or the government.

⁶⁵ *Centers for Medicare and Medicaid Services Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals*: Government Accountability Office, GAO-04-850, 2004

standards by Centers for Medicare and Medicaid Services through its periodic audits of each accreditation agency.⁶⁶

Medicare and private plans assume peer review in hospitals is robust, particularly when a hospital is accredited by the Joint Commission. Medicare Contractors and private payers assume that negligent care cannot be hidden from peers over many years. Even if peer review is broken temporarily, insurers believe other physicians at the hospital will not tolerate it long and take effective action to correct it. All these assumptions are unsupported because the Medicare Condition of Participation requirements are not enforced.

Consistent peer review will improve patient care. Physician performance feedback will modify physician behavior and improve health outcomes.⁶⁷ Performance feedback can be based on review of care of specific cases, compliance with surrogate markers of outcomes (e.g. aspirin use in acute coronary syndromes), or actual patient outcomes (e.g. hospital length of stay or mortality for a particular disease).

There are two principal methods to find cases to review: (1) through complaints by health care professionals or patients, and (2) through chart audits. In a study, Ann O'Neil (1993)⁶⁸ compared chart audits with anonymous case reporting. More preventable events were discovered via anonymous reporting (62.5%) compared with patient chart audit (32%) ($p = 0.003$). The cost per case review was less for the anonymous method: \$15,000 v. \$54,000. Anonymous reports are more effective and less expensive than serial chart audits. Yet, in a study published in the *Annals of Internal Medicine*, Campbell⁶⁹ found that when physicians discover a quality of care problem due to an incompetent or impaired colleague, 45% of problems are not reported -- even though 96 percent agreed that they should turn in such people. We recommend Agency for Healthcare Research and Quality conduct a detailed survey to determine the reasons a physician may under-report incompetent services and propose corrective remedies. Agency for Healthcare

⁶⁶ The American Osteopathic Association's Healthcare Facility Accreditation Program also has deeming authority for hospitals, granted by Congress. The requirement for an accreditation organization to provide services across the nation can be found in the Social Security Act at § 1865(b)(1):

"...if the Secretary finds that accreditation of a provider entity (as defined in paragraph (4)) by the American Osteopathic Association or any other national accreditation body demonstrates that..."

[Emphasis added]

§1865(b)(4) "For the purposes of this section, the term "provider entity" means a provider of services, supplier, facility, clinic, agency, or laboratory."

The requirement to be a national accreditation body applies to all accreditation organizations applying for deeming authority, not just those seeking deeming authority for hospitals.

⁶⁷ Wenghofer EF, Way D, Moxam RS, Wu H, Faulkner D, Klass DJ.; *Effectiveness of an enhanced peer assessment program: introducing education into regulatory assessment. Health Serv Res.* 2005 Apr;40(2):459-76.

⁶⁸ O'Neil, Anne C; *Physician Reporting Compared with Medical Record Review to Identify Adverse Medical Events*; *Annals of Internal Medicine*, 1993 September 1, vol 119, issue 5. From Brigham and Women's Hospital, Boston, Massachusetts; the Harvard School of Public Health, Boston, Massachusetts.

⁶⁹ Campbell et al. *Professionalism in Medicine: Results of a National Survey of Physicians.* *Annals of Internal Medicine*, 2007 December 4, vol 147: 795-802.

Research and Quality should publish the results and solicit remedies from the provider community.

Our findings suggest that effective in-house peer review requires:

1. Hospital administrative support of the medical staff to conduct peer review,
2. Alignment of incentives where peer reviewers are positively reinforced,
3. Qualified medical staff member participation,
4. Diligent performance of peer review,
5. Proper funding and compensation of reviewers outside of the control of a hospital,
6. Methods to protect a reviewer from retaliation,⁷⁰
7. A culture and process that encourages reporting of adverse events including anonymous reporting,
8. An opportunity for outside peer review upon request by any involved party,
9. Effective oversight of the process by:
 - a. Medical staff committees
 - b. Medical directors of clinical departments
 - c. The medical staff executive committee
 - d. The hospital's board of directors
 - e. Government agencies
10. We also recommend that hospitals:
 - a. Provide to treating physicians comparable patient outcomes data (e.g. mortality, length of stay) adjusted by the severity of illness,⁷¹
 - b. Provide performance feedback and recommendations to treating physicians,
 - c. Conduct chart audits based on predetermined quality measures with performance feedback to treating physicians and medical staff,
 - d. Fund a random review medical images reports for accuracy, particularly those read by treating physicians.

We recommend Congress create a National Patient Safety Board analogous to the National Transportation Safety Board, as a vehicle to conduct disaster analysis and propose corrective action. Hospitals are similar in their services, systems, and processes; therefore, problems and remedies discovered through a disaster analysis may be relevant to many other hospitals.

LEGISLATIVE AND AGENCY REMEDIES:

In summary, we propose the following changes:

1. **Intermediate Sanctions:** Congress should provide Centers for Medicare and Medicaid Services with the authority to impose intermediate sanctions against hospitals and physicians, including loss of provider status for selected services

⁷⁰ Physicians who participate and take peer review seriously may be punished by loss of referrals or favor from other physicians and or hospital administrators.

⁷¹ In the Redding Medical Center case, this information would have supported Dr. Moon and Dr. Realyvasquez as excellent physicians because their complication rates were low and they falsely diagnosed illness.

- until patient safety and quality is assured, and stopping payment for elective services in a department where peer review is absent
2. **Detailed Payment Audits:** When a peer review deficiency is discovered, Centers for Medicare and Medicaid Services should employ its Contractors to conduct detailed audits for medical necessity, quality of care, and medical negligence, starting with the chief of the department and the high billers.
 3. **Deemed Status:** Congress should give the Health and Human Services Secretary the authority to confer deeming authority for hospital accreditation organizations, congruent to Health and Human Services' authority over clinical labs under Clinical Laboratory Improvement Amendments (CLIA) 88 and Durable Medical Equipment, Prosthetics, Orthotics, and Supply providers under Medicare Modernization Act. Deemed Status: Congress should give the Health and Human Services Secretary the authority to confer deeming authority for hospital accreditation organizations, congruent to Health and Human Services' authority over clinical labs under CLIA 88 and Durable Medical Equipment, Prosthetics, Orthotics, and Supply providers under MMA 2003.
 4. **Competition Among Accrediting Organizations:** Congress should promote opportunities for additional organizations to provide accreditation services as is done under CLIA and Durable Medical Equipment, Prosthetics, Orthotics, and Supply providers and investigate what barrier currently exists for market entry.
 5. **Anonymous Reporting:** Medical Staff by-laws under federal requirements should permit and encourage anonymous reporting of physician errors.
 6. **Independent Peer Review:** State laws, under federal mandate if needed, should provide for non-conflicted and independent peer review by experts from outside the institution when needed.
 7. **Compliance Standards:** The standards for compliance with the Condition of Participation must include all aspects of peer review and quality oversight. Violation of any element must be sufficient to find the entire Condition is violated.
 8. **Disaster Analysis by a National Patient Safety Board:** Establishment of a NPSB of the purpose of disaster analysis and system wide implementation of remedies' when applicable. i.e. When law enforcement or other agencies identifies physician negligence in a hospital lasting for a long period of time (e.g. more than two years), the case should prompt a detailed analysis of the hospital peer review system and the competency of the hospital accrediting organization, under an assumption that peer review has failed (similar to an analysis by the NTSB in an airline disaster) so that the recommendations can be implemented system wide when applicable.
 9. **National Practitioner Data Bank Analysis:** The appropriate federal agency should finance a study of the confidential data contained in the National Practitioner Data Bank to determine why hospitals' are reporting so few peer review actions of moderate to high capability physician errors.
 10. **Peer Review Suppression:** Congress should determine how conflicts of interest impair the peer review process and consider appropriate remedies. This includes hospital recruitment contracts and salary guarantees for more than two years or entry level salaries above the market. Congress should focus on the role of

hospital owners, how clinical department directors are appointed and their role in peer review, the role of contracted physicians to provide peer review, how the medical staff functions are funded, and related issues regarding hospital control of peer review.

11. **Peer Review Conference:** Congress should fund a conference of peer-review experts to recommend studies and methods to evaluate and improve peer review.
12. **Interagency Communication:** States should provide for better interagency communication when a violation of a Medicare Condition of Participation that affects patient safety and quality is detected. The agency should consider that the violation could be deliberate in order to make money for the physician and the institution. It should communicate its findings with Medicare contractors, private insurers, and the state medical board. High volume, high dollar cases should be reviewed by an interagency team to determine the need for pre-payment review, post-pay audit, and review of specific peer reviewed cases.
13. **Plan of Correction Requirement:** When a plan of correction is required of a hospital and agreed upon by the State, the state agency (e.g. California Department of Health Services Licensing and Certification Division) should be given the authority to require the hospital to follow it. If the Plan of Correction is changed, the institution should be required to explain the reason for the change and gain approval of the change by the approving agency.
14. **Department Directors:** When peer review is found absent or inadequate, and is not promptly corrected, the responsible physician department director should be removed as part of the Plan of Correction.
15. **Review of Accreditation Quality:** Should a State or Centers for Medicare and Medicaid Services surveyor find a Condition of Participation or Title XXII violation by hospital that was accredited at the time the deficiency existed, the accrediting agency should be audited for negligent accreditation. Remedies should be made available to Centers for Medicare and Medicaid Services to correct negligent accreditation.
16. **Educate the Public:** The federal government should provide an internet site to educate the public and medical staff on matters of hospital safety, accreditation, hospital accreditation status, the accuracy rate of accrediting agencies' surveys compared with State surveys, and findings from accrediting agencies' audits. Physicians who are finishing their residency programs should be encouraged to review the site to help choose a hospital and practice location.
17. **New Technology:** When new technology is adopted, its use should be carefully reviewed to be sure it is used properly. The mentors and reviewers brought in should not be conflicted, (e.g. paid by the company selling the technology).