I. THE ROLE OF PEER REVIEW IN HOSPITAL COMPLIANCE PROGRAMS

In its Supplemental Compliance Program Guidance for Hospitals (Federal Register, Vol. 69, No. 110/June 8, 2004), the OIG identifies a number of “fraud and abuse risk areas” which relate directly to hospital based peer review or medical staff activities:

- Submitting claims for medically unnecessary services;
- Hospital – physician relationships in violation of the Fraud and Abuse statute or Stark II;
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(continued)

- Payments to reduce or limit services – gainsharing arrangements;
- EMTALA compliance;
- Substandard care; and
- General interest - professional courtesy arrangements.

A. The role of peer review/Medical Staff activities in avoiding medically unnecessary services.

Joint Commission Accreditation Standards mandate.

Medical Staff organization both self-governing and responsible to the Governing Body for the quality of patient care in the facility;
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(continued)

Medical Staff functions to include effective utilization review.

Conditions of Medicare Participation obligate hospitals to have effective utilization review/management committees. (42 CFR Part 482-30).

Typically, utilization review/management committees are organized as Medical Staff committees including practitioners, administrative personnel and "Physician Advisors."

Utilization review/management committees review the medical appropriateness of admissions; duration of stays; and professional services furnished.

If an admission, continued staff or services is found not medically necessary, the committee issues notice to the hospital, patient and providers. Such notices may lead to denial of Medicare or Medicaid payment.
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(continued)

Utilization review committees may also initiate corrective action / disciplinary investigation in accord with Medical Staff bylaws.

CONCERN: Utilization review/management committees may be affected by conflicts of interest between hospital representatives pushing for lower length of staff (higher reimbursement per DRG) and practitioners paid on a fee for service basis.

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(continued)

CONCERN: Physician organizations often accuse hospitals of using utilization review/management committees for “economic credentialing.”

Systematic failure to control medically unnecessary care may lead to catastrophic Qui Tam actions, OIG enforcement actions, or both. (Redding Medical Center).
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(continued)

B. The Medical Staff and compliance with Fraud and Abuse / Stark II

1. General

The Fraud and Abuse statute prohibits the payment or receipt of any form of remuneration if any purpose is to induce patient referrals. 42 USC 1320a–7(b)(1). “Safe harbors” have been published to identify permitted relationships. 42 CFR Section 1001.952

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(continued)

Stark II prohibits a physician from referring patients to any entity (such as a hospital) for covered services (including hospital inpatient services) if the physician or a family member has an ownership interest in or a financial arrangement with the entity; unless, an express exception applies. 42 CFR Part 411.
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(continued)

2. Typical “accommodations” provided to Medical Staff members.

Stark II exceptions exist for certain common accommodations provided by hospitals to staff members:

a. Non-Monetary compensation up to $329 aggregate per practitioner per year (inflation adjusted). May not be based on referrals, solicited, or intended to induce referrals. Individual limits may not be combined for gifts to practice groups. 42 CFR Section 411.357 (k).

This is intended to cover lunches, gift baskets, sport events and similar gifts.
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   (continued)

   b. Medical Staff incidental benefits of up to $28 per item (inflation adjusted) provided on campus while practitioners are working. Must be available to all staff members in the same specialty without regard to referrals. 42 CFR Section 411.357 (m).

   This is intended to cover such items as parking, free lunch, lab coats.

   c. Free Transportation Services

   Hospitals may offer free transportation services for patients to cover transportation from a patient home or physician office to the hospital for services. May only be within hospital’s primary service area and must be offered to all medically suitable patients. OIG letter of Industry Guidance Branch re: complimentary local transportation program, December 9, 2002.
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(continued)

d. Compliance Training

Hospitals may offer free training to assist Medical Staff members and their staffs comply with Medicare, Stark II and other legal requirements. 42 CFR Section 411.357 (o).

This exception does not apply to free CME required to maintain a physicians license.

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3. Contracts to compensate Medical Staff officers or members who perform administrative services related to clinical services. 42 CFR Section 411.357 (e).

Hospitals commonly compensation the chief of staff or other Medical Staff officers and often compensate key staff members to provide administrative services related to clinical services.
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(continued)

These officer and medical director agreements must comply with safe harbor and exception provisions for “personal service arrangements.”

Covered services must be necessary; compensation must not exceed “fair market value;” agreements must be in writing for a term of at least 12 months; and, they may not be intended to induce referrals.

4. Other peer review related policies with compliance implications.

Conditioning medical staff membership or privileges on minimum admission/utilization standards.
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Granting emergency call panel participation opportunities based on admissions or utilization.

Enforcing “conflict of interest” provisions baring staff members from relationships with other facilities.

5. Other Safe Harbors and Exceptions which may affect peer review.
   - Physician ownership in entire hospital facility.
   - Space and equipment leases.
   - Physician referral services.
   - Physician recruitment.
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(continued)

- Malpractice insurance subsidy for obstetrics.
- Joint Venture Arrangements.
- Physician contributions to charitable entities.
- Community wide health information systems.
- Bona fide employment.

C. Gainsharing Arrangements – Payments to Reduce or Limit Services

Some hospitals have considered entering into arrangements with medical staff members to share savings resulting from efforts to standardize use of equipment or supplies, or, otherwise to increase efficiency in patient care. OIG opinion letter of January 20, 2005.
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In one case, OIG indicated it did not intend enforcement action where a hospital agreed to share savings with surgical staff resulting from using standardized surgical trays. That statement was based on assurances that the arrangement was not intended to affect the volume of services provided and that the percent of savings paid to the surgeons was set in advance.

OIG has stressed that payments to reduce or limit services may violate the Civil Monetary Penalty Act; Fraud and Abuse or Stark II.

D. EMTALA Compliance

One of the most difficult aspects of EMTALA compliance is for hospitals to maintain reliable and effective emergency call panel arrangements for services provided at the facility. See, CMS Revised Emergency Medical Treatment and Labor Act (EMTALA) Interpretive Guidelines May 13, 2004; 42 CFR Section 489.24 (j).
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(continued)

It is often difficult or impossible to maintain full call coverage for all specialties (especially, neurosurgery, orthopedic surgery, ENT).

Call panel arrangements are often addressed in Medical Staff bylaws or rules and can become the basis of contention between the Medical Staff and hospital governance.

Increasingly, hospitals enter into compensation arrangements with call panel members. Such arrangements must meet criteria for “Personal Services Agreements.” Reaching agreement on compensation may also be complicated by antitrust considerations or by perceived discrimination among specialty groups.

Call panel members sometimes resist their obligation under EMTALA to come into the emergency department to evaluate or care for patients – at the discretion of the Emergency Department physician.
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(continued)

Some Medical Staff organizations have attempted to reduce call panel burdens by requiring staff members to be responsible to provide emergency call services for patients for whom they have professional or contract relationships. Such arrangements must not result in delay of needed care.

E. Substandard Care

The primary goal of peer review and Medical Staff activity is to promote high quality patient care.

A finding of substandard patient care, may result in expedited loss of Medicare provider status as well as adverse licensure or accreditation action. And, hospital corporations in many states are liable for negligent credentialing or review of staff members.
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Medical Staff officers, hospital administrators and Board members are all obligated to assure that Medical Staff committees and clinical departments actually function as described in bylaws and rules and are conscientious about quality assurance.

F. Professional Courtesy Arrangements

A Stark II exception permits “professional courtesy” policies involving free or reduced cost for services for physicians and their family members or staff; provided the services are made available to all staff or community physicians without regard to referrals or business generated; cover items and services routinely provided by the facility; the policy is in writing and approved by the facility’s board; and the policy complies with federal programs relating to financial need and with co-insurance requirements. 42 CFR Section 411.357 (s).
II. ROADBLOCKS TO EFFECTIVE PEER REVIEW

Practitioners’ natural disinclination to criticize colleagues.

Perceived or actual conflicts of interests involving individuals, practice groups, or sub-specialist groups.

Lack of reliable comparative statistics relating to mortality, morbidity, complications.

II. ROADBLOCKS TO EFFECTIVE PEER REVIEW (Continued)

Conflicts between physicians and nurses. Perceived and actual unwillingness of physicians to accept or credit criticism from nursing staff.

Enormous cost in money and time to prosecute medical disciplinary actions.

Retaliatory threats or litigation by practitioners – techniques to circumvent the duty to exhaust hospital-based hearing and appeal rights before suing for damages.
III. SOME RECENT JUDICIAL DECISIONS – HELPING OR HURTING PEER REVIEW

A. The California Supreme Court has struck a blow against practitioners’ retaliatory litigation.

Kibler v. Northern Inyo County Local Hospital District (Cal.Sup. Ct., July 20, 2006)
The MEC summarily suspended Dr. George Kibler in December 2002, based on evidence that he had “exhibited escalating unprofessional conduct of extremely hostile and threatening verbal assaults, threats of physical violence, including assault with a gun, and related erratic actions of a hostile nature toward nursing and administrative personnel.”

On January 3, 2003, Dr. Kibler’s privileges were reinstated following execution of a good conduct agreement and a court injunction.

On December 13, 2003, Dr. Kibler filed a lawsuit against the hospital and certain physicians and nurses alleging various torts.

Finding that hospital peer review is an “official proceeding authorized by law” the California Supreme Court ordered Dr. Kibler’s suit dismissed.

Some lower courts had ruled that peer review in private hospitals is not an “official proceeding” authorized by law.
III. SOME RECENT JUDICIAL DECISIONS – HELPING OR HURTING PEER REVIEW (continued)

B. Some California Court of Appeal Districts have promoted effective peer review by applying procedural rules flexibly.

Mileikowsky v. Encino Tarzana Regional Medical Center, et al. (Cal. Appeal Court 2005).
- Physician with history of chronic behavior problems and disruption of the peer review process. During two separate hearings, physician refused to comply with hearing officer rulings on disclosure of documents and other procedural rulings.

- Physician continuously interrupted hearing with threats, outbursts and repeated violation of hearing officer’s rulings to avoid comments on related litigation. When physician refused to agree in writing that he would comply with rulings, hearing officer ruled he had waived his right to a hearing.

- Court of Appeal found hearing officer had implied authority for the ruling despite absence of specific bylaws provision.

**Tolwin v. Cedars-Sinai Medical Center**  
• Key Facts:

April 1998 – VPMA imposes summary restriction on Dr. Michael Tolwin’s psychiatric privileges in the form of a mandatory departmental review of his next ten admissions.

The peer review committee recommended immediate termination of privileges.

• May 1998 – VPMA summarily suspends Dr. Tolwin’s privileges and recommends termination.

• 1998-2000 – thirty hearing sessions

• February 2003 – Hearing Committee finds Dr. Tolwin “failed to meet applicable standards of care;” exhibited “significant clinical deficiencies;” had “significant issues with documentation and legibility;” and failed to address concerns and self-correct.
• Hearing Committee determined that the April 1998 summary restriction was reasonable and warranted.

• **But:** Hearing Committee determined that although the VPMA acted reasonably when he imposed the May 1998 summary suspension, the suspension should be “rescinded” and Dr. Tolwin should be immediately reinstated with conditions, including monitoring and education.

• MEC (following bylaws) automatically reviewed Hearing Committee decision and concluded the evidence did not support the Hearing Committee’s recommendation that the May 1998 suspension should be rescinded.

• MEC recommended the Board should uphold the May 1998 summary suspension and that reinstatement should be subject to proctoring.
• On appeal, the Board agreed with the MEC that the May 1998 summary suspension was proper and that the MEC’s conditions for reinstatement were also proper.

• In his mandate lawsuit, Dr. Tolwin argued the Board was obligated to uphold the Hearing Committee’s rescinding of the summary suspension, because it was supported by substantial evidence.

• **DISCUSSION POINT:** What difference does it make? Liability implications?

• Dr. Tolwin also argued the MEC had acted as “trier of fact” and so should have been subject to the procedural requirements of BP 809.
• **Judicial Rulings:**

The Court found that the MEC’s Interim review was legal and that the MEC was not the trier of fact under BP 809.

The Court also found that the Board on appeal was not limited to determining whether the Hearing Committee’s decision was supported by substantial evidence. Both the MEC and the Board were entitled to exercise their independent judgment to evaluate the evidence.

**Discussion Point:** Significance of Board review standard on appeal.

Finally, the Court ruled that the reasonableness of the May 1998 summary suspension must be evaluated based on the information available at that time, not based on the additional information presented to the Hearing Committee.
III. SOME RECENT JUDICIAL DECISIONS – HELPING OR HURTING PEER REVIEW (continued)

C. Another California Court of Appeal District Complicated Peer Review By Erecting New Standards for Hearing Officers.

Yaqub v. Salinas Valley Memorial Hospital (2004)
California Court of Appeal finds violation of fair procedure where hearing officer appointed by hospital had history of contacts with hospital as mediator, hearing officer and member of foundation board.

III. SOME RECENT JUDICIAL DECISIONS – HELPING OR HURTING PEER REVIEW (continued)

D. Two Federal District Court have Increased the Risk of Taking Actions and Reporting Practitioners.
Poliner v. Texas Health Systems (ND Texas, March 27, 2006).

• Key Facts:

Dr. Lawrence R. Poliner, cardiologist, admitted to medical staff of Presbyterian Hospital of Dallas: Provisional (1996); Full (October, 1997).

Incident report filed September 29, 1997: patient death following cath lab procedure.
Incident report filed October 29, 1997: patient suffered stroke following cath lab procedure.

Incident report filed December 18, 1997: alleged use of contaminated sheath in cath lab.

Incidents referred to Department of Internal Medicine for Review.

During review, cath lab director reports, Dr. Poliner performed angioplasty on wrong artery.

Chairman of Internal Medicine Department, Dr. James Knochel, meets with Dr. Poliner on May 14, 1998, while cases still under department review.

Dr. Knochel “demands” Dr. Poliner voluntarily agree not to exercise cath lab privileges pending review of cases. “Abeyance” later found to have been an involuntary summary suspension without following bylaw provisions.

Ad Hoc Committee reports substandard care in 29 of 44 cases. May 20, 1998.
Internal Medicine Advisory Committee (IMAC) recommends review of echocardiograms with outside reviewer; suggested continuance of “abeyance.”

Dr. Poliner agrees to extension of “abeyance” until June 12, 1998.

Dr. Poliner requests more time to respond to review. Dr. Knochel refuses.

IMAC votes unanimously to suspend Dr. Poliner’s cath lab privileges.

Formal medical staff hearing conducted – November 1998. Hearing Panel approves summary suspension, but restores Dr. Poliner’s privileges with conditions.

• **Legal Claims:**

  - State and federal antitrust.
  - State torts: violation of due process; defamation; unlawful interference with practice; infliction of emotional distress.

• **Preliminary Rulings:**

  - Peer review documents ordered to be produced in Federal Court.
  - Antitrust claims dismissed – no harm to “competition.”
• Dr. Poliner allowed to sue for denial of due process.

• Defendants did not qualify for immunity under Health Care Quality Improvement Act.
  * Abeyance action not provided for in bylaws.
  * Abeyance action not based on reasonable investigation of facts.
  * Note: Hearing committee later restored privileges.

• Jury Verdict:

  $366 million; including $110 million in punitive damages (subject to mediation and possible remittitur).
• Note:

• California exhaustion of remedies rule would not apply to claims based on “abeyance” for which there was no remedy to exhaust.

• Huge risk attaches to informal, non-bylaw based resolutions.

• Voluntary “abeyance” under threat, is not voluntary.

Kadlec Medical Center v. Lakeview Anesthesia Associates, et al. (ED La., May 19, 2005)
• Key Facts:

• Dr. Robert Lee Berry practiced anesthesiology at Louisiana Regional Medical Center (“LRMC”) as employee of Lakewood Anesthesia Associates (“LAA”) from January 1997 to March 2001.

• 2002 audit of narcotic medication records determined Dr. Berry had failed to properly document withdrawals of Demerol.

• March 13, 2001, Dr. Berry found sedated and sleeping on chair while on duty.

• Dr. Berry terminated by LAA that day.
• Dr. Berry’s privileges at LRMC expired.

• Later, Dr. Berry obtained privileges at Kadlec Medical Center (Washington).

• Kadlec sent “Appointment Reference Questionnaire” asking for information about Dr. Berry’s qualifications and evaluations.

• LRMC responded with dates of membership but declined to provide detailed information, citing “standard business practice.” Later it was determined that LRMC did provide detailed evaluations for other applicants.

• In 2002, Dr. Berry was anesthesiologist for tubal ligation surgery. Patient suffered extensive brain damage resulting in $7.5 million settlement against Kadlec.
• **Claims:**
  
  • Kadlec sued LRMC, LAA and individuals involved in filing the response letter.
  
  • Intentional misrepresentation.
  
  • Negligent misrepresentation.

• **Analysis**
  
  • Federal Court determines defendants had a duty to disclose adverse information to Kadlec based on “special” “confidential” relationship between requesting and responding facility.

  • “This court finds that when a hospital chooses to respond to an employment referral questionnaire, public policy should encourage a hospital to disclose the sort of information at issue.”
• “LRMC’s direct response omitted relevant and material information about [Dr. Berry’s] tenure which may have been exceedingly useful in preventing the harm caused Kadlec among others.”

• “Kadlec has presented sufficient evidence of an intent to deceive [including evidence that] LRMC’s response to its inquiry and questionnaire was substantially different from responses sent by LRMC to other hospitals requesting similar information about other doctors….”

• Comment:
  - Would California courts find liability for responding incompletely to credentialing requests?
  - School districts and personnel provided positive employee recommendations for assistant principal, Robert Gadams, despite evidence that he had sexual inappropriate interactions with junior high school girls.
• Relying on those recommendations, Livingston Middle School employed Mr. Gadams where he sexually molested plaintiff, Randi W.

• California Supreme Court upheld liability of former districts and personnel.

• While defendants had no obligation to affirmatively say anything about Principal Gadams, if they provided any information, they were obligated to provide all material information available to them, including evidence that the Principal had reportedly been involved in improper sexual situations with school girls.