

White Paper: Managing Conflict of Interest in Hospital Peer Review

For Hospital Groups, ASCs and Specialty Medical Facilities

Executive Summary

Risk of conflict of interest (COI) presents a very real threat to the success and credibility of any organization, and the potential for is inherent in any healthcare organization. In simplest terms, a COI exists when a set of circumstances creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest. Managing COI is an essential component of maintaining quality and integrity. Nowhere is this more important than in hospitals, where COI can compromise the integrity of the physician peer review process.

Hospitals regularly perform peer review in order to ensure that their physicians are properly credentialed, competent, and trained to safely treat patients, while providing the highest standard of care. An internal peer review program carries the potential for COI arising from social or professional relationships, or from too few physicians being available in a particular specialty. If not identified and properly managed, COI within peer review can lead to a breakdown in a hospital's physician performance improvement program and quality management system, jeopardizing patient safety and putting the hospital at risk.

In light of recent media coverage of serious consequences resulting from alleged COI among hospitals and physicians, hospital medical staff, quality and risk management professionals are starting to recognize the importance of removing COI from the peer review process. In order to avoid COI concerns during all physician evaluations and to ensure patient safety and quality care, a hospital should develop and communicate its policy and expectations regarding COI to its staff and have a policy in place that stipulates when it is necessary to engage external reviewers.

The use of external peer review can help hospitals avoid COI that can arise from economic, professional or social ties among physicians within a single institution, and it may also be an effective solution to complement internal review processes in hospitals that lack adequate physician resources to conduct timely performance evaluations. It is the hospital leadership team's responsibility to develop a culture that supports peer review by using it primarily as an educational, not disciplinary, tool.

A survey of nearly 3,000 physicians, published in the Journal of the American Medical Association in 2010, found that about one third who knew of an incompetent colleague did not report the person to the relevant authorities, even though the AMA has a code of ethics that states that doctors have an ethical obligation to report such behavior

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Introduction

According to the American Medical Association (AMA), conflict of interest (COI) is not completely avoidable in the hospital setting. A COI is a situation in which financial, professional or other personal considerations have the potential to compromise or bias professional judgment and objectivity. A physician peer reviewer with a COI is ethically obligated to disclose it to the rest of the peer review committee. It is the peer review committee's job to identify COI prior to assigning case reviews and/or determine whether a conflict is substantial enough that the peer reviewer should not be involved in making a case determination. Most of these decisions are judgment calls, but such judgments are easier when backed by sound medical staff bylaws and clear policies and procedures.

A COI can be either real or apparent. A real COI exists when a reviewer has a professional, financial or other personal interest that prevents him or her from making an unbiased determination, providing unbiased advice, exercising independent judgment, or being objective with respect to evaluating the case. An apparent COI occurs when personal interests raise questions about a reviewer's ability to review a case fairly. Peer reviewers who have a personal interest in cases must recuse themselves in order to avoid scrutiny for impropriety. Some COI situations, however, are not as clear-cut.

Why COI is the No. 1 Impediment to Effective Peer Review

Hospitals perform peer review to ensure that their physicians are properly credentialed, privileged, competent, and adequately trained to safely treat patients, by evaluating performance to ensure high quality care. Unfortunately, the process can be flawed if peer review is handled only internally. Internal peer review carries the potential for COI, or the difficulty of holding a colleague accountable, especially if there are social or professional relationships or too few physicians in a specialty.

Physician Authority and Autonomy

Physicians have long been regarded as figures of power, and this authority is legitimized by the licensing process through its restrictions on who can practice medicine. Physicians also have the freedom to exercise their judgment in the best interest of the patient without interference. This autonomy is based on the premise that physicians will act competently and put the well being of the patient ahead of their own personal interests. In some cases, the hospital's culture may be so focused on physician authority and autonomy that the MEC, peer review committee, medical staff or administration may be reluctant to review a physician's performance through the peer review process.

Unspoken Rules of the Organization

The unspoken rules of an organization may prevent physicians from reporting medical errors. A survey of nearly 3,000 physicians, published in the Journal of the American Medical Association in 2010, found that about one third who knew of an incompetent colleague did not report the person to the relevant authorities, even though the AMA has a code of ethics that states that doctors have an ethical obligation to report such behavior. Reasons for not reporting included the belief that someone else would take action, the belief that nothing would happen as a result of a report, and the fear of retribution. The authors concluded that this atmosphere exposes patients to unacceptable risks.

Potential Shortcomings of the Peer Review Committee

Most hospitals initially refer cases to department peer review committees. These committees often act with little oversight from the medical executive committee, which results in a lack of uniformity in the peer review process, as well as inconsistent application of protocols and procedures across all specialties.

Some physicians simply do not have the training or experience to conduct effective peer review. For others, involvement in a peer review committee presents yet another time-consuming responsibility to add to an already overloaded sched-

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ule. Physicians' heavy workloads often delay the peer review process, preventing the implementation of quality-of-care improvements that the process is intended to oversee. In some cases, reviews are not given the attention they require.

Consequences of Not Managing COI

One landmark case that clearly illustrates the consequences of not managing COI, as well as failure of the peer review process, took place at Redding Medical Center (RMC) in Redding, California. Between 1992 and 2002, cardiologists and cardiac surgeons at RMC performed unnecessary procedures and operations on more than 600 patients, with the encouragement of hospital leadership.

Documents indicate that quality assurance personnel repeatedly certified or accredited the institution throughout this period despite records showing that peer review was not performed beginning as early as 1992. According to the report, the hospital administration acted to protect its cardiac program from quality and peer review because patient care suspected to be negligent was so profitable; high-ranking hospital officials, the hospital administration, and members of the medical staff leadership repeatedly ignored quality complaints.

Whenever possible, also avoid assigning a case to a physician reviewer if the reviewer actively practices in the same hospital as the physician under review

Only after discovery by the FBI in 2002, were the physicians and hospital officials stopped. They eventually paid about \$500 million in combined negligence awards and the hospital was sold. The valuation and reputation of the corporation that owned the hospital was seriously compromised.

The Joint Commission and the Centers for Medicare & Medicaid Services Standards

In 2007, the Joint Commission instituted new standards for monitoring performance and intervening when safety and quality-of-care concerns are identified. According to the standards, hospitals of all sizes are required to demonstrate that objective decision-making is in place in the credentialing and privileging of their physicians. The Joint Commission requires two types of reviews to ensure physician competence: ongoing professional practice evaluation (OPPE) and focused professional practice evaluation (FPPE). As hospital credentialing and privileging requirements call for more comprehensive peer reviews, hospital administrators and internal peer review committees must always consider COI when conducting focused or ongoing evaluations.

According to case review guidelines set forth by the Centers for Medicare & Medicaid Services (CMS), every effort should be made to avoid potential COI. The CMS guidelines also state: "Whenever possible, also avoid assigning a case to a physician reviewer if the reviewer actively practices in the same hospital as the physician under review. Finally, avoid potential COI when selecting physicians to serve on your quality improvement and sanction committees."

How to Manage COI

Hospital quality and risk managers are starting to recognize the importance of removing COI from the peer review process. In order to avoid COI concerns during all physician evaluations and to ensure accountability and transparency that improves quality care, a hospital should develop and communicate expectations, policies and procedures regarding COI to its staff and have a policy in place explaining when it is necessary to engage external reviewers. Boards must be particularly vigilant with respect to their own COI because they are responsible for patient safety and ensuring that quality care is upheld.

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Effective Leadership

Effective peer review requires a centralized multidisciplinary peer review system that utilizes a uniform method for peer review activities. The peer review system should be designed with a strong multidisciplinary peer review committee established as a subcommittee of the medical executive committee (MEC), which is ultimately responsible to the board for ensuring that the peer review program is carried out by its medical staff in accordance with the intent and procedures documented in the organization's peer review policies. The peer review committee should have overall jurisdiction for the operation of the peer review system, assuring the MEC that all required peer review procedures and required program elements are effectively implemented. This is especially true for identifying and eliminating COI.

In the past, many hospital boards typically focused on financial issues (e.g., fund raising, capital expenditures, operating margins) and delegated oversight of clinical matters to the medical staff. However, increased scrutiny of institutional leadership in general and pressure to improve quality and safety in hospitals now presents the challenge to hospital boards and medical staff members to work together to optimize quality of care and patient safety.

Although both the board and medical staff are accountable to improve quality of care, they often address this duty independently. The board must engage the medical staff by becoming more involved in and educated about the quality of care provided in their institutions and by recruiting physicians to join the governing body. Likewise, the medical staff should understand the unique duties of the board, which may help the two parties resolve conflicts that may arise from divergent goals or strategies. Regardless of their differences, both entities must work together to ensure that the peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues.

The medical staff bylaws should also address the various situations in which COI must be considered so that safety and quality of care are not compromised.

Medical Staff Bylaws

The medical staff bylaws of a hospital define the governance structure and functions of the medical staff. With regard to COI, the AMA recommends that "Candidates for election or appointment to medical staff offices, department or committee chairs, or the medical executive committee, should disclose in writing to the medical staff, prior to the date of election or appointment, any personal, professional or financial affiliations or responsibilities on behalf of the medical staff." The medical staff bylaws should also address the various situations in which COI must be considered so that safety and quality of care are not compromised.

Policies and Procedures

The Institute of Medicine (IOM) Committee on Conflict of Interest in Medical Research, Education, and Practice recommends that medical institutions establish COI policies that require disclosure and management of both individual and institutional financial ties. According to the IOM, institutions should create a COI committee to evaluate these ties. If necessary, a board-level committee should deal with COI at the institutional level. The Committee recognizes that current policies are highly variable, and recommends standardizing the content, format, and procedures for disclosing any COI. (Please see Appendix A for a sample COI policy for medical staff.)

The challenges of managing COI are significant, and failure to adequately address COI poses risk to not only the institution and its patients, but also to the progress of health care. In addition to developing and implementing policies and procedures for managing COI, hospitals must continually evaluate existing policies and revise them if necessary.

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Training on COI

Physicians conducting reviews should be educated about all potential COI issues. Hospitals must understand the web of economic, competitive, and social or personal relationships that might raise concerns. Whenever a reviewer is in a professional partnership, competes for patients, or socializes with the physician undergoing review, the question of COI arises. An educated reviewer will alert the committee chair when a conflict exists and request an alternate reviewer. If a suitable one is not available, the committee chair should seek an external peer review.

Auditing of COI

A hospital can successfully manage the social and professional relationships among its medical staff members once it recognizes these ties, using established transparent standards. The ongoing evaluation requirement can be met by randomly selecting several cases from all practitioners. Some hospitals schedule rotating ongoing evaluations of their medical staff several times a year with independent review organizations (IROs) to eliminate COI concerns about their reviews.

Potential COI in Different Specialties

Potential COI are not limited to any one particular specialty. Many hospitals must deal with a limited number of specialists on staff, which increases the potential for professional or personal relationships, just as smaller hospital groups and hospitals in smaller communities face the challenge of matching specialists because the pool of specialists is smaller and the potential for COI is higher.

To meet quality of care guidelines, ensure objectivity, and bring about positive outcomes to protect patients, practitioners must review only others who are “like specialists.” That is, cardiologists should review cardiologists, not other internal medical specialists. Similarly, general practitioners may not have the training or experience in the multidimensional approaches to treatment or have the most up-to-date information for standards of care used in specialties such as interventional cardiology or neurosurgery. An evidence-based approach requires review of actual work performed by a specialist with the same credentials and practice experience.

Ignoring probable COI opens the door for a “conflicted” specialist physician to review another involuntarily. In the long term, this can only decrease the quality of care and compromise patient safety. In extreme cases, it can put the hospital at risk for loss of accreditation, sanctions, steep penalties, damaged reputation, and even possible jail time for the parties involved.

Interventional Cardiology Example

In 2010, a Maryland hospital agreed to pay a \$22 million fine to settle charges that it paid illegal kickbacks to a cardiologist’s practice in exchange for patient referrals. Reports indicate that the cardiologist may have implanted more than 500 stents that were medically unnecessary, with Medicare paying \$3.8 million of the \$6.6 million charged for those procedures. According to a hospital statement, “The medical center reached the agreement without admitting any liability in order to avoid the expense and uncertainty of litigation and to allow the medical center to move forward.”

Neurosurgery Example

One neurosurgeon in Oregon lost his operating privileges at the hospital where he performed many of his surgeries and is under investigation by the Oregon Medical Board after performing multiple spinal fusions on individual patients, with a rate nearly 10 times the national average. Recent information has also emerged highlighting his relationship with the medical-device distributor that supplied him with spinal implants. The neurosurgeon denies any wrongdoing and said he acted in the best interest of his patients. However, a malpractice lawsuit filed against the physician in April 2011 was the ninth in less than 7 years.

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In both of the above examples, a well-defined and executed peer review process that was free from COI could have potentially avoided financial and reputation issues that were a consequence of this lack of oversight.

The Role of External Peer Review in Managing COI

As stated above, conflicts of interest frequently arise in peer review situations, as reviewers often have economic, professional, social, or family ties with the physician undergoing review. Many hospitals do not have a sufficient number of practitioners in a given specialty to assign a reviewer without such ties. An objective outside determination can mitigate the threat of allegations of biased peer review. It can also identify problems in hospital processes or procedures that should be corrected to reduce the likelihood of similar problems in the future. In cases where the review is the result of an incident or pattern that may lead to litigation or corrective action, hospitals may wish to consider engaging an objective outside expert sooner, rather than later. Finally, an objective outside determination can help establish a defensible paper trail supporting the rationale for the hospital's position.

Individual hospitals should develop procedures to turn to external peer review as required by their own particular circumstances. Hospitals with high volume and few willing or qualified reviewers may decide to outsource all cases in a particular specialty, or a certain number of cases at regular intervals, quarterly, semi-annually or annually. Cases in which internal reviewers cannot reach a conclusion or a consensus should be subject to external peer review, as should unresolved quality issues related to a particular department, procedure, or practitioner. In addition, cases in which physician behavior or demeanor may have had an impact on clinical outcomes benefit from objective outside review by a peer with no prior personal knowledge of the physician.

Conclusions

Conflict of interest is one of the most difficult issues to overcome when colleagues working together at the same hospital conduct peer reviews. Managing COI is especially important with the expanded role of peer review through focused and ongoing evaluation processes. Any internal peer evaluation must always factor COI situations into its process; failure to do so may result in serious consequences that can permanently damage a hospital's reputation and a physician's career. In order to effectively manage COI, hospitals must educate their leaders and medical staff and establish clear expectations, policies and procedures, as well as clearly define when external peer review is necessary.

A hospital's internal peer review process may trigger the need for external peer review, not only when there is a COI among available reviewers, but also when there is a lack of clinical expertise among available reviewers, when findings are ambiguous or conflicting, or when there is a lack of a strong consensus for a finding. When properly executed, external peer review can reduce medical errors through objective evaluations performed in a non-punitive, educational context that supports a healthy culture of continual improvement.

Increased transparency and accountability is a byproduct of physicians knowing that their work will be objectively evaluated at regular intervals by board-certified specialists with the same credentials and from similar practice settings, thereby leading to improved quality of care and patient safety and, over time reducing a hospital's professional liability claims and costs. Ongoing evaluation of physicians can also uncover problematic practice patterns, as well as physician- and hospital-level issues that need to be addressed.

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Appendix A: SAMPLE CONFLICT OF INTEREST POLICY & PROCEDURE

ABC Hospital, Inc.

Title: *Conflict of Interest Policy for Medical Staff*

Formulated By:

Applies To: *ABC Hospital Medical Staff*

Effective: *7/11*

Purpose:

To safeguard the integrity and reputation of ABC Hospital, Inc. (FACILITY) and its medical staff by fostering the proper and unbiased conduct of all medical staff activities. This policy serves to educate medical staff members about situations that generate conflicts of interest, to provide a means for the medical staff and FACILITY to disclose and manage conflicts of interest, to promote the best interests of the community, patients, their families, employees, the governing board and other practitioners, and to describe situations that are prohibited.

Policy:

An actual, potential or perceived conflict of interest may occur if a FACILITY medical staff member's outside activities and personal interests such as financial interests, business or family relationships, influence or have the appearance of influencing his or her ability to make objective decisions during his/her medical staff duties with other medical staff members, patients, or hospital staff. A potential conflict of interest exists when a member of the medical staff or an Immediate Family Member stands to directly or indirectly gain as a result of a decision. A conflict of interest depends on the situation and not on the character of the individual. It is inappropriate for the actions or decisions of a medical staff member made in the course of his/her FACILITY activities to be determined or influenced by considerations of professional or personal interests or financial gain. Such behavior calls into question the professional objectivity and ethics of the individual, and it also reflects negatively on the organization.

Medical Staff members must conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts in interest arise. The following are representative, but not all inclusive, of conflict of interest situations:

- ▶ Participation in a peer review process that involves real or apparent conflict of interest due to pre-existing social, business, economic or professional relationship that would influence the objective evaluation of a practitioner's performance.
- ▶ Identification and reporting of medical errors, performance deficiencies or quality of care concerns that arise in the course of working with colleagues or evaluating their work in a care setting.
- ▶ Influence on purchases of equipment, instruments, materials or services for use by FACILITY from the private firms in which the medical staff member, or an Immediate Family Member, has a Material Financial Interest.
- ▶ Unauthorized disclosures of patient or FACILITY information for personal gain.
- ▶ Giving, offering, or promising anything of value, as a representative of FACILITY, to any government official to enhance relations with that official or the government.
- ▶ Transmission to a private firm or other use for personal gain of FACILITY supported work, products, results, materials, record, or information that are not made generally available.

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- ▶ Influence upon the negotiation of contracts between FACILITY and private organizations with which the medical staff member, or Immediate Family Member, has a Material Financial Interest, or will receive favorable treatment as a result of such influence.
- ▶ Improper use of FACILITY resources for personal financial gain.
- ▶ Acceptance of compensation or free services from a vendor, service provider, or contractor of FACILITY, when the medical staff member is in a position to determine or influence the organization's purchases from those persons.
- ▶ A Material Financial Interest in suppliers or competitors of FACILITY in the healthcare industry.

Procedure:

1. Disclosure: Whenever a medical staff member is in a situation where he/she may have a conflict of interest, that member should request an exemption by making a full disclosure in writing of the details of the situation. This disclosure should be submitted to the Chief of Staff and Chief Medical Officer. The Medical Staff Conflict of Interest Disclosure Form should be completed upon approval of this Policy for existing members of the Medical Staff and upon reappointment for new members.

The Chief of Staff and Chief Medical Officer and his/her designees shall review the situation and examine all facts thoroughly for apparent conflicts. If the Chief of Staff and Chief Medical Officer determine that FACILITY would best be served by the granting of the requested they may do so in writing with justification for the granting and delineating of any conditions placed on the approval. If the Chief of Staff and the Chief Medical Officer determine that no exception should be granted, the medical staff bylaws process shall be followed.

It is a violation of this policy to fail to disclose a conflict of interest when it is know or reasonably should be known to the medical staff member.

2. Reporting: Suspected violations of this policy should be reported to the Medical Executive Committee. Such reports may be made confidentially, and even anonymously, although the more information given, the easier it is to investigate the reports. Raising such concerns will not jeopardize anyone's employment or medical staff membership.

All violations of laws or regulations as determined by above stated process will be forwarded to the Compliance Officer. Disciplinary action will be taken in accordance with the Medical Staff Bylaws.

Related Documents:

- ▶ FACILITY Medical Staff Bylaws, Rules and Regulations
- ▶ Peer Review Committee Policy on External Peer Review
- ▶ Human Resources Policy on Conflict of Interest
- ▶ Patient Rights and Organizational Ethics Policy
- ▶ Code of Ethical Behavior Policy
- ▶ Legal Compliance Program