Model Principles for Incident-Based Peer Review for Health Care Facilities

June 2005



Every physician matters, each patient counts.

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Introduction

The demands for accountability in health care, and advancement in patient safety and quality of care require objective and systematic evaluation and improvement of care given by physicians and the entire care team. Some examples in this upsurge are the many efforts at improving patient safety in the Institute of Medicine's report on medical errors¹, the Massachusetts Board of Registration in Medicine's Patient Care Assessment (PCA) Program², the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) new national patient safety goals³ and the enactment of the Health Care Quality Improvement Act of 1986 (HCQIA)⁴ by the US Congress.

Review of physician performance by peers is a time-honored way of achieving this accountability and has obvious merits and done properly is most effective. The public has entrusted the profession (as a "learned profession") with the responsibility of self-regulation. In 1993, it was estimated that 1 in 20 physicians will undergo an incident based peer review process and 1 in 5 will serve on a peer review committee to evaluate an alleged quality problem. There has been, however, some erosion of public confidence in the process. In addition, within the profession, there are two concerns. One is that systems to identify and improve poor quality have little teeth due to the paucity of adequate remedial resources. The second is that lack of objectivity and due process may make peer review, as is currently practiced, ineffective and may create innocent victims out of competent physicians, deprive patients of their services, and expose physician reviewers to legal liability. "Given the magnitude of the resources devoted to quality assurance and the centrality of peer assessment to these efforts, there is a need for a global reexamination of the peer review process." This report focuses on the issues raised by incident based peer review at health care entities, where the majority of such peer review occurs.

The peer review process triggered by an adverse or sentinel event may vary greatly between organizations. Physicians often know little about the details of the process in their own institutions and about the scientific and legal framework for peer review. Recent research and anecdotal evidence suggests that physicians are not generally fully aware of the key role played by medical staff bylaws in peer review at hospitals nor are they participating effectively in the creation or modification of these bylaws. In incident based peer review, as practiced, the demarcation between the quality improvement effort and the disciplinary process is not always clear. While the quality improvement process depends on confidentiality and free expression, due process is the bedrock for the disciplinary aspect.

Current peer evaluations are often based on anecdotal or incidental approaches rather than statistical approaches. The trigger is often an untoward event or a surrogate marker (e.g. a patient returning to the operating room) related to a physician's care. That physician's performance (and not others who may have quality problems) in the subject case and, at times other past cases, may be evaluated against an ill-defined "standard of care." Some studies have shown that the rate of agreement among reviewers for overall quality problems in single cases is poor except in cases of egregious error where the relevant standard is obvious. To 11, 12, 13, 14, 15, 16, 17, 18, 19, 20 If judged to be "below the standard" by colleagues in the hospital who may be the subject physician's economic competitors and may have "opinions" about the subject physician based on unsubstantiated "facts" and innuendos from the past, the physician may be sanctioned based upon such unidentified "evidence" that would generally be considered inadmissible.

Hospital bylaws may not always provide adequate due process, and courts are loathe to secondguess peer review committees. State laws²² provide for confidentiality of peer review and the Federal Health Care Quality Improvement Act of 1986 ("HCQIA"),²³ as well as a number of state laws²⁴ provide legal immunity to peer review bodies as a means to encourage improvement of health care. As an additional disincentive to challenges to peer review proceedings, the HCQIA permits a court to award costs and attorneys fees to the prevailing party "if the claim or the claimant's conduct during the litigation of the claim was frivolous, unreasonable, without foundation or in bad faith." ²⁵

The combination of confidentiality and immunity provisions, while encouraging the use of peer review as a quality improvement tool, severely limits external scrutiny of the process used or its outcome. The limitations on external oversight make it even more essential that the peer review process is performed appropriately at the local level. The mandatory requirement to report actions that adversely affect the physician's clinical privileges for thirty days or more, however minor the quality of care issue is, to the National Practitioner Data Bank (NPDB), may make a negative peer review action a career death knell for the physician by resultant health plan deselection from current panels and from inability to join other health plans or hospital staff. While the stakes are high, some physicians have concluded "[t]he immunity afforded participants in peer review has emboldened groups to use the peer review process as a weapon to control competition within a community."²⁶ Physicians who feel they have been improperly sanctioned and venture to seek legal redress against these odds are further confronted by the reality that they and their attorneys may be sanctioned and liable for the peer review entity's costs and attorneys fees if a court finds the challenge to the peer review action to be frivolous, unreasonable, without foundation or prosecuted in bad faith. ^{27, 28, 29, 30}

Bias, fear of reprisal and the potential for reviewer liability may make it near impossible to identify and address the deficiencies of physicians who may be "popular" or "well connected" and yet associated with quality of care that is "below the standard." Another related factor is the possible reluctance to commence a peer review process for a less than severe quality problem because of the mandatory reporting requirements and the potential for career-ending effect of such reporting to the NPDB and state regulatory entities.³¹

Much effort and many resources are invested by a number of entities in the current system of incident based individual case review for quality of care improvement with little objective evidence to indicate success, yet causing very significant burdens and sometimes harm to good doctors. ^{32, 33, 34, 35}

Peer review as currently practiced, along with the statutory confidentiality and immunity protections, creates a potential for abuse without checks and balances. The potential exists for competent physicians to lose their ability to practice resulting in patients' loss of good physicians and an atmosphere of decreased access and competition. The laws offer substantial, but not complete, protection to physician participants from adverse effects resulting from being critical of colleagues, and the subject physician is not completely protected from bad faith review. Despite their intent, peer review laws by themselves cannot ensure quality health care. The potential exists for competent physicians to lose their ability and immunity protections, creates and balances. The potential exists for competent physicians to lose their ability and immunity protections, creates and balances. The potential exists for competent physicians to lose their ability and immunity protections, creates and competent physicians and an atmosphere of decreased access and competition. The laws offer substantial, but not complete, protection to physician participants from adverse effects resulting from being critical of colleagues, and the subject physician is not completely protected from bad faith review.

It behooves the profession; therefore, to ensure that peer review as required under our law is, in fact, effective in achieving the goal of quality improvement, while being fair, transparent and credible.

I. Improving Quality of Patient Care

Quality improvement is the goal of peer review. The public wants to be assured that the profession is doing all it can for quality improvement, and the profession wants the process of peer review to be objective, effective, fair and not onerous.

A. Massachusetts Law

Massachusetts law provides for institution-based peer review as well as monitoring of quality by the Massachusetts Board of Registration in Medicine (BRM). In addition to its disciplinary function, the BRM has a separate, confidential quality assurance program. The Patient Care Assessment (PCA) program of the BRM, established pursuant to M.G.L. c.112, § 5 and M.G.L. c.111, § 203, is responsible for the oversight of all Massachusetts health care facilities' systems of quality

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assurance, risk management, peer review, utilization review and credentialing in order to improve the quality of health services. Hospital participation in the program is mandated as a condition of hospital licensure.³⁸ It includes detailed reporting.³⁹ In addition, the bylaws of every hospital and medical staff must establish an internal process for "reporting conduct by a health care provider that indicates incompetency" or "might be inconsistent with or harmful to good patient care or safety." The bylaws are also required to "direct a procedure for investigation, review and resolution of such reports." Appropriately constituted medical peer review committees are accorded specific confidentiality and immunity protections by statute. ⁴¹

B. Federal Law

The federal HCQIA seeks to promote quality improvement through two basic methods: establishment of the NPDB, which collects in one place information about sanctions against physicians nation wide based upon quality of care, thereby preventing physician evasion of the sanctions, and the provision of immunity from monetary damages for peer review committees which meet minimum due process standards.

C. Conclusions

Resolution through sanctions, though customary and aimed at "weeding out the bad apples," is useful only in extreme circumstances. ⁴² Having carefully identified outliers, the aim of the majority of peer review activities must be to help outlier physicians through remediation. The resolution should also include system evaluation and system remediation to achieve total quality management.43, ⁴⁴

In order to translate these very strong safeguards and assurance to the public into effective application, the MMS Committee on Medical Service, with consultation on ethical principles from the Committee on Ethics and Discipline, has developed principles for the conduct of peer review in these circumstances:

- 1. to continually improve the quality of care through promoting principles for the conduct of peer review in health facility settings that will encourage more comprehensive reporting without fear of reprisal; and create a focus on remediation; and to
- 2. improve the effectiveness of the process of peer review in health facility settings through
 - minimizing bias
 - allowing scrutiny; and
 - ensuring due process in any sanction proceedings.

These principles followed thoughtfully and diligently will not only promote quality improvement in health care, but also the trust of the public and the profession essential to achieve that important goal.

II. Confidentiality

Confidentiality of the identity of the patients involved, the details of the event(s) and the proceedings of the peer review committee are all essential for free discussion to help improve the quality of patient care. Fear that the information may be used by the professional liability plaintiff's bar or for adverse publicity or sanction inhibits the reporting and free discussion of care issues, which discussions are necessary to improve care quality.

A. Massachusetts Law

Massachusetts law provides for extensive confidentiality protections for the proceedings of a peer review committee with few specified exceptions, one such being the formal proceedings of the Boards of Registration in Medicine, Social Work or Psychology. 45

The PCA program of the Massachusetts BRM requires hospitals to report events along with steps taken to improve quality while not identifying the patient or the physicians involved. The

confidentiality of the information, records and reports obtained or created to comply with the PCA program is protected by M.G.L. c.111,

§ 204 and § 205. Information provided to the Massachusetts Department of Public Health, however, does not enjoy such confidentiality protection.

B. Federal Law

Federal laws do not provide for confidentiality of peer review proceedings. When addressing federal claims, a number of federal courts have permitted discovery of peer review materials. While recognizing the importance of peer review, courts have noted that there is no statutory basis in federal law for a peer review privilege, and they have declined to recognize a common law privilege in cases where preserving confidentiality of peer review materials would frustrate vindication of a federal right.⁴⁶

C. Conclusions

The confidentiality provisions are not intended to prevent substantive information from being shared with the participants in the peer review process including the physician whose care is being evaluated (subject physician). Such sharing and participation by the subject physician is essential to fully analyze the circumstances, draw valid conclusions and make improvements for the future. It is equally important for all the facts used by a peer review committee, and any conclusion(s) and proposed sanction(s) be made available to the subject physician to ensure fairness and due process. The withholding of essential information from subject physicians has hampered full analysis of events and due process in some situations, causing erosion of physician trust in the process.⁴⁷ Since the confidentiality protections preclude external scrutiny, it is very important that the peer review process take these considerations into account fully in the first instance.

Fairness, transparency and due process are important in themselves and are also important to insulate against challenges to the confidentiality of the peer review proceedings and materials.

III. Immunity

Physicians are committed to quality improvement and volunteer to serve on peer review boards for that reason. Fear of legal liability dampens the enthusiasm. Hence, federal and Massachusetts laws provide immunity from monetary damages for peer review committees, and their reviewers, staff and advisors.

A. Massachusetts Law

M.G.L. c. 111 § 203(c), along with M.G.L. c. 231, § 85N, provides immunity for peer review committees and their members and those providing information, opinion, counsel or services to the committees from liability in law suits for actions or omissions in this service, provided the individuals or the institution "acted in good faith and with a reasonable belief that said actions were warranted in connection with or in furtherance of the function of the committee."

B. Federal Law

Following a very sizeable award against a peer review board in a case involving Anti-competitive considerations, ⁴⁸ the US Congress enacted the HCQIA ⁴⁹ providing immunity to peer reviewers.

This federal immunity is very substantial and prohibits the award of monetary damages against the peer review committee and reviewers for allegations (including state and federal antitrust, tort and other claims) from any private person. However, there is no immunity for civil rights violations, antitrust actions by the government or injunctive or declaratory relief. Besides the immunity, HCQIA also provides that a physician who unsuccessfully challenges the outcome of a peer

review proceeding in court can be required to pay the attorney fees of the hospital and the peer review entity.

To qualify for federal immunity, the HCQIA requires that certain standards be met by the peer review process:

"Fairness" standards:

The professional review must be undertaken:

- 1. In the reasonable belief that it is in the furtherance of quality of health care; and
- 2. After a reasonable effort to obtain the facts in the matter; and
- 3. After "adequate notice and hearing" procedures are afforded the physician involved, or after such other procedures as are fair to the physician under the circumstances; and
- 4. 4) In the reasonable belief that it was warranted by the facts after a reasonable effort to obtain the facts and after meeting the requirements listed in the "adequate notice and hearing" standard #3 above.

HCQIA provides that if the following "safe harbor" conditions are met, the peer review action will be deemed to have satisfied the "adequate notice and hearing" standards to qualify for immunity. The following examples of other standards may satisfy the requirements but only if the court finds them to be "adequate."

"Safe harbor" for "adequate notice and hearing" standards:

- 1. The physician is given notice stating (1) that a professional review action has been proposed to be taken against the physician, (2) the reasons for the proposed action, (3) that the physician has the right to request a hearing on the proposed action, (4) any time limit (of no less than 30 days) within which to request such a hearing, and (5) a summary of the rights in the hearing.
- The physician who requests a hearing is then given a notice that states (1) the place, time
 and date of hearing, which date cannot be less than 30 days after the date of the notice, and
 (2) a list of witnesses (if any) expected to testify at the hearing on behalf of the professional
 review body.
- 3. The hearing is held (1) before an arbitrator mutually acceptable to the parties, or (2) before a hearing officer or panel of individuals who are not in direct economic competition with the physician.
- 4. At the hearing, the physician has the right to (1) be represented by an attorney or other person of choice, (2) have a record made of the proceedings (and to obtain copies of such record at the physician's expense), (3) call, examine, and cross examine witnesses, (4) present relevant evidence, and (5) submit a written statement at the close of the hearing.
- 5. Upon completion of the hearing, the physician has the right to receive the arbitrator's or panel's written recommendations, including the basis of the recommendation and to receive the written decision of the health care entity, including a statement of the basis for the decision.

C. Conclusions

The immunity protections are very powerful and difficult to overcome, which gives physicians great comfort while serving on peer review panels and confidence to the public that physicians can act in the interest of quality improvement without fear of reprisal. In case of a miscarried peer review conclusion or sanction, the subject physician has very limited recourse. Federal immunity is based upon the process being "fair." Effective use of the peer review process hinges upon fairness and due process.

IV. Triggering the Peer Review Process

A critical step in the peer review process is the initiating event. Typically, the process involves a screening scheme that identifies clinical events thought to be associated with an increased likelihood of practice irregularities (e.g., blood transfusion or unexpected return of a patient to the operating room). The advantage of such a system is that non-physician personnel can perform initial screening. Unfortunately, by necessity, screening criteria must be concrete. Therefore, they are typically not very sensitive. This makes it difficult to identify early potential system problems and "near misses." In addition, such a process is not "risk adjusted," so there is a selection bias against individuals in high-risk practices.

Another common triggering mechanism is the so-called "adverse incident." The care provided a patient who suffered an untoward outcome is reviewed. This method also has serious drawbacks. Adverse events are sporadic, so patterns of care are not easily determinable.

To encourage voluntary reporting of incidents and "near misses" the process needs to provide for deidentification of reports and focus on a systems correction approach rather than a punitive approach.

Early review of cases selected through informally screening with the subject physician often reveals information and issues which then permit resolution of the case to achieve the necessary quality improvement through means other than the formal peer review process.

To be effective, triggers should be evidence based or of general acceptance, usage and validity. For fairness and for quality improvement reasons, the triggers must be available to all member physicians and must be uniformly applied to all cases and physicians. However, the initial review should take into account case mix severity of the cases/physician reviewed.

V. Peer Review for Quality Improvement vs. Disciplinary Process

Incident based peer review aims to allow participants to learn from the events reviewed and improve future quality—what is traditionally achieved through "M&M (morbidity and mortality) conferences."

The term "peer review" as used here and in federal and state statutes is generally understood to include any resultant disciplinary process. ⁵⁰ However, the latter can in fact be viewed as distinct from the fact finding and learning process. The disciplinary process may use the findings of the quality review and impose punitive sanctions. These sanctions are required to be reported to various agencies, including the NPDB, which is the other half of what was established by the HCQIA. Such reporting has serious consequences for the subject physician and her/his patients.

There is an increasing feeling that these mandatory reporting laws have transformed the peer review process from an evaluative and corrective process to one that has become excessively punitive in nature. ⁵¹ It should not be lost that remediation holds the potential for saving a physician's career and serving the public interest. ⁵²

The distinction between the two roles of peer review is more than academic. To achieve full benefit from peer review as a learning tool, there needs to be confidentiality and immunity protections to promote free exchange of information and ideas behind closed doors. To sanction effectively and fairly, protect the public interest (public interest requires dangerous doctors to be removed, and good doctors not be removed for anticompetitive or inappropriate reasons) and maintain confidence in the process, there need to be due process and free flow of information to the subject physician and transparency of the process to stakeholders, including physicians and the public.

Often, there is no clear line of demarcation when the process moves from one phase to the other. It is therefore important to clearly identify when the process is beginning to move to one of considering sanctions. All involved parties including the subject physician must be clearly notified at that point and

the physician should be given appropriate due process. At no point should maintaining confidentiality be used to withhold relevant information from the subject physician. Such withholding is counterproductive to the goals of learning as well as that of due process. When a deviation from the standard of care is alleged, the subject physician must be given adequate access to the records of the alleged failure and the records demonstrating the "relevant standard of care." De-identification of the records, where possible, as to patient and physician, will help preserve confidentiality and objectivity.

VI. Bias

There is potential for bias of various kinds at several points in the review:

A. Bias extrinsic to medical factors:

- 1. Economic competitor on the peer review body
- 2. Economic competitor testimony to the body
- 3. Peer review body member's prior independent "knowledge" (rumors, "common knowledge," etc.) of physician performance or the subject case ("jury selection" criteria)
- 4. External pressures (e.g. "public" eagerness to find the cause or a solution; institutional or group pressure; institutional or referral source obligations)
- 5. Political impediments to peer review of a "popular" physician's quality of care
- 6. Unlawful discrimination (e.g. race, gender, national origin) or prejudice against person perceived as different from dominant group.

Using the following elements in peer review may reduce bias extrinsic to medical factors:

- "Distancing" the peer reviewers from the subject physician (e.g. using reviewers from another institution; the state or county specialty society)
- Blinding reviewers to the identity of the patient(s) and physician(s)

B. Intrinsic bias in review process:

- 1. Systematic and random bias
- 2. Lenient vs. strict considerations (institutional, individual, related to time)
- 3. Knowledge of severity of outcome
- 4. Knowledge of the effect of the outcome on patient/family

C. Individual reviewer bias:

- 1. Background and training
- 2. Past experience
- 3. Preferences

Bias listed under categories B and C may be reduced using:

- Multiple reviewers
- Structured review tools
- Statistical comparison methods

Case mix adjustment for severity

- Blinding reviewers to the medical outcome while reviewing the process of care
- Education and training in peer review principles and practice for physicians serving on the board.

VII. Reliability and Validity of Implicit Review

Evaluation of the process of care is time-consuming and best done by practitioners of the same training as the practitioner involved in the incident. Although this method permits evaluation of the general quality of care and can cover the totality of the care provided, it is in practice very often subjective. In implicit case review, the method used in incident based peer review of individual cases, the criteria for determining judgments are not expressly stated, and a reviewer uses her or his own undefined criteria to assess the quality of care. ⁵³

As noted earlier, most studies find agreement between physicians regarding quality of care to be only slightly better than the level expected by chance⁵⁴ except in egregious error where the relevant standard is obvious.^{55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65} The possible reasons for the high level of inter-rater disagreement include bias (discussed above), complex nature of medical practice and lack of conclusive evidence, the lack of uniform assessment tools, and the general lack of formal training in peer review.⁶⁶ Such poor interrater agreement on appropriateness of care challenges the validity of implicit case review by peers.67, 68, 69

Evaluating the process of care in clinical situations with poor outcome or major patient and family impact is prone to the bias of hindsight.70, ⁷¹ Incident based peer review, which follows the identification of an adverse or proxy event and then the reviewing of the related care, is inherently vulnerable to bias from this knowledge. Blinding the reviewers, where feasible, to the outcome and its impact, will help minimize bias.

Use of multiple reviewers and review using structured tools and training in the process of review seem likely to increase the reliability of review.⁷²

We accordingly recommend the following method of evaluation:

- Statistical comparison of subject physician's and other physicians' performance over the same period (long enough and with enough volume) using de-identified (as to patient and as to physician) clinical data would be a more reliable tool than implicit single case review. Case mix adjustment for severity of illness would be required to make meaningful comparison.
- If statistical comparison of adequate volume is not feasible, case review with comparison to all such cases done by all physicians over an extended period of time with allowance for case severity would allow comparison to a "local standard of care."
- If neither of these is available, a single case study may be used, but only if the deviation is egregious and the relevant standard is obvious. Multiple reviewers, blinding and distancing become ever more important under these circumstances.

VIII. Findings from the Review

The goal of peer review is quality improvement. While the findings in some cases may necessitate a sanction of the subject physician, the goal is still quality improvement, and remedial recommendations are important to achieve this goal. The focus of the review should extend beyond the individual physician's performance to include assessment of the operational environment in which the clinician functions⁷³ as

most mal-occurrences are not due to the action, inaction or misjudgments of one person but result from multiple breakdowns. 74,75

It has been suggested that the peer review process should enable threshold decision making, whether the physician's performance or behavior and their pattern lend themselves to corrective action or whether they call for punitive action or removal from practice as a public protective measure.⁷⁶

At the conclusion of the review, a written report detailing the issues and recommendations for quality improvement will serve the main goal of quality improvement. If no specific quality improvement recommendations are made, the effort would not serve its full purpose. The report must be made available to the subject physician. The report must address the relevant system issues.

The report should detail at least the following with specifics and not in vague or general terms (such as "problematic," "questionable," "not meeting the standard," "inappropriate"):

- The identified deviation (act or omission) in the process of care from the "standard of care"
- The "standard of care" from which the deviation occurred
- The source for the above "standard of care"
- What specific steps of care should have been taken or not taken to meet the "standard of care"
- What specific remediation, if any, is recommended for the physician (whenever feasible, in terms that permit measurement and validation of remediation, when completed).
- What specific remediation, if any, is recommended for system failures (whenever feasible, in terms that permit measurement and validation of remediation, when completed).

IX. Due Process and Appeals

The interests of quality improvement and fairness to the physician involved and her/his patients and the public at large are well served by transparency of the process and following the HCQIA guidelines as a minimum requirement for proceedings where there is the potential for discipline. This will also bolster the trust of the profession and the public in the process. The minimal external review or scrutiny of an institutional peer review decision as discussed earlier makes it imperative to conduct the process with impeccable fairness and following the principles diligently and allowing a meaningful appeal of any disciplinary finding.

It has been suggested that incident based implicit peer review be regarded as a rough screening test because of its poor reliability and validity and that at a minimum a second level review be conducted by experienced reviewers with an explicit format based on available practice guidelines.⁷⁷ Use of a different panel (than the one that made the original determination) to hear any secondary review or appeal will increase objectivity and credibility.

X. Knowledge of Process and Training

The general level of awareness regarding the process of peer review is very low among physicians and needs to be much improved if peer review is to serve its purpose well. Many physicians are not adequately aware of the process of peer review or the laws governing these nor even their own institutional bylaws or their rights or obligations in this regard until they face a peer review process. That's certainly not the time to learn about the process if the intent of the process – quality improvement – and essential ingredients in the process—participation and fairness – are to be achieved. As outlined above, peer review committee members need an even greater degree of learning and training to serve effectively.

Hospital and other institutional leadership need education in the process and limitations of incident based peer review, the principles for effective peer review and the applicable laws. In addition, the institutions would benefit from physician input into appropriate institutional bylaws. Medical staff

members need to be well informed about the process and the importance of active participation in the bylaw creation and revision process so that these principles may become an integral part of self-governance and the improvement of the quality of the care their patients receive.

XI. Acknowledgements

These Model Principles for Incident-Based Peer Review for Health Care Facilities were created through the collaborative work of the Committee on Medical Service (Subramanyan Jaysankar, MD, Chair 2003) and the Committee on Ethics and Grievances (David F. Gouveia, MD, Chair 2003). Additionally, the committee chairs would like to acknowledge the following MMS committees and section:

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These principles are based upon existing state and federal laws, guidelines and policies of the Joint Commission on the Accreditation of Health Care Organizations, and the American Medical Association.

THE INFORMATION PROVIDED IN THIS BOOKLET IS INTENDED TO SERVE AS A GENERAL RESOURCE AND GUIDE. IT IS NOT TO BE CONSTUED AS LEGAL ADVICE. READERS WITH SPECIFIC LEGAL QUESTIONS SHOULD CONSULT WITH A PRIVATE ATTORNEY.

Appendices

- Health Care Quality Improvement Act of 1986 (HCQIA) requirements State Law re: confidentiality, immunity
- The Patient Care Assessment (PCA) Program of the Board of Registration in Medicine
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards
- Massachusetts Medical Society (MMS) Policies
- American Medical Association (AMA) Policies and letter from AMA leadership regarding compliance with HCQIA.

(AMA and California Medical Association Model Bylaws available upon request to the Department of Health Policy/Health Systems)

Appendix 1

Health Care Quality Improvement Act of 1986

Due Process Standards (42 USC Sec. 11112)

TITLE 42 - THE PUBLIC HEALTH AND WELFARE

CHAPTER 117 – ENCOURAGING GOOD FAITH PROFESSIONAL REVIEW ACTIVITIES **SUBCHAPTER I** – PROMOTION OF PROFESSIONAL REVIEW ACTIVITIES

Sec. 11112. Standards for professional review actions

- (a) **In general**—For purposes of the protection set forth in section 11111(a) of this title, a professional review action must be taken
 - (1) in the reasonable belief that the action was in the furtherance of quality health care,
 - (2) after a reasonable effort to obtain the facts of the matter,
 - (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and
 - (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

A professional review action shall be presumed to have met the preceding standards necessary for the protection set out in section 11111(a) of this title unless the presumption is rebutted by a preponderance of the evidence

- (b) **Adequate notice and hearing**—A health care entity is deemed to have met the adequate notice and hearing requirement of subsection (a)(3) of this section with respect to a physician if the following conditions are met (or are waived voluntarily by the physician):
 - (1) Notice of proposed action—The physician has been given notice stating
 - (A) (i) that a professional review action has been proposed to be taken against the physician,
 - (A) (ii) reasons for the proposed action,
 - (B) (i) that the physician has the right to request a hearing on the proposed action,
 - (B) (ii) any time limit (of not less than 30 days) within which to request such a hearing, and
 - (C) a summary of the rights in the hearing under paragraph (3).
 - (2) Notice of hearing—If a hearing is requested on a timely basis under paragraph (1)(B), the physician involved must be given notice stating
 - (A) the place, time, and date, of the hearing, which date shall not be less than 30 days after the date of the notice, and
 - (B) a list of the witnesses (if any) expected to testify at the hearing on behalf of the professional review body.
 - (3) Conduct of hearing and notice—If a hearing is requested on a timely basis under paragraph (1)(B)
 - (A) subject to subparagraph (B), the hearing shall be held (as determined by the health care entity)
 - (i) before an arbitrator mutually acceptable to the physician and the health care entity,

- (ii) before a hearing officer who is appointed by the entity and who is not in direct economic competition with the physician involved, or
- (iii) before a panel of individuals who are appointed by the entity and are not in direct economic competition with the physician involved;
- (B) the right to the hearing may be forfeited if the physician fails, without good cause, to appear;
- (C) in the hearing the physician involved has the right
 - (i) to representation by an attorney or other person of the physician's choice,
 - (ii) to have a record made of the proceedings, copies of which may be obtained by the physician upon payment of any reasonable charges associated with the preparation thereof.
 - (iii) to call, examine, and cross-examine witnesses,
 - (iv) to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law, and
 - (v) to submit a written statement at the close of the hearing; and
- (D) upon completion of the hearing, the physician involved has the right
 - (i) to receive the written recommendation of the arbitrator, officer, or panel, including a statement of the basis for the recommendations, and
 - (ii) to receive a written decision of the health care entity, including a statement of the basis for the decision.

A professional review body's failure to meet the conditions described in this subsection shall not, in itself, constitute failure to meet the standards of subsection (a)(3) of this section.

- (c) Adequate procedures in investigations or health emergencies—For purposes of section
 - 11111(a) of this title, nothing in this section shall be construed as
 - (1) requiring the procedures referred to in subsection (a)(3) of this section
 - (A) where there is no adverse professional review action taken, or
 - (B) in the case of a suspension or restriction of clinical privileges, for a period of not longer than 14 days, during which an investigation is being conducted to determine the need for a professional review action; or
 - (2) precluding an immediate suspension or restriction of clinical privileges, subject to subsequent notice and hearing or other adequate procedures, where the failure to take such an action may result in an imminent danger to the health of any individual.

Appendix 2

Massachusetts Statutes

The current laws governing medical peer review in Massachusetts are stated under Massachusetts General Laws (M.G.L.) Chapter 111, Sections 1, 203-205, and Chapter 231, Section 85N.

M.G.L. c. 111, § 1: Definition of a medical peer review committee

M.G.L. c. 111, § 1 defines "medical peer review committee" or "committee" as a committee of a state or local professional society of health care providers, including doctors of chiropractic, or of a medical staff of a licensed hospital or nursing home or health maintenance organization organized under chapter one hundred and seventy-six G, provided the medical staff operated pursuant to written by-laws that have been approved by the governing board of the hospital or nursing home or health maintenance organization, which committee has as its function the evaluation or improvement of the quality of health care rendered by providers of health care services, the determination whether the cost of health care services were performed in compliance with the applicable standards of care, determination whether the cost of health care services rendered was considered reasonable by the providers of health services in the area, the determination of whether a health care provider's actions call into question such health care provider's fitness to provide health care services, or the evaluation and assistance of health care providers impaired or allegedly impaired by reason of alcohol, drugs, physical disability, mental instability or otherwise; provided, however, that for purposes of sections two hundred and three and two hundred and four, a nonprofit corporation, the sole voting member of which is a professional society having as members persons who are licensed to practice medicine, shall be considered a medical peer review committee; provided, further, that its primary purpose is the evaluation and assistance of health care providers impaired or allegedly impaired by reason of alcohol, drugs, physical disability, mental instability or otherwise.

M.G.L. c. 111, § 203: Provider misconduct; medical peer review

- § 203 (a) The by-laws of every licensed hospital and the by-laws of all medical staffs shall contain provisions for reporting conduct by a health care provider that indicates incompetency in his specialty or conduct that might be inconsistent with or harmful to good patient care or safety. Said by-laws shall direct a procedure for investigation, review and resolutions of such reports.
- § 203 (b) Whenever, following review by a medical peer review committee of a licensed hospital determination is reached that a health care provider's privileges should be suspended in the best interests of patient care, such committee shall immediately forward the recommendation to the executive committee of the medical staff and the institution's board of trustees for action. A provider whose privileges are suspended shall be entitled to notice and a prompt hearing following suspension, in accordance with the institution's medical staff by-laws.
- § 203 (c) An individual or institution, including a licensed hospital, physician credentialing verification service operated by a society or organization of medical professionals for the purpose of providing credentialing information to health care entities, or licensed nursing home reporting, providing information, opinion, counsel or services to a medical peer review committee, or participation in the procedures required by this section, shall not be liable in a suit for damages by reason of having furnished such information, opinion, counsel or services or by reason of such participation, provided, that such individual or institution acted in good faith and with a reasonable belief that said actions were warranted in connection with or in furtherance of the function of said committee or the procedures required by this section.

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- § 203 (d) Every licensed hospital shall, as a condition of licensure, be required to participate in
 risk management programs established by the board of registration in medicine pursuant to
 section five of chapter one hundred and twelve; provided, however, that licensed hospitals
 which participate in pre-existing risk management programs may be exempted by regulations of
 the board from the requirements of this paragraph.
- § 203 (e) Every licensed nursing home shall:
- (i) request from every physician providing medical care in the nursing home said physician's name and license number;
- (ii) upon initial appointment of its medical director or physician advisor and biennially thereafter, inquire from a hospital where the physician has staff privileges and spends the greatest portion of his time, the status of said physician's staff privileges, or if the physician has no such staff privileges, make such reasonable inquiry, as the board of registration in medicine by regulation may require, into the physician's employment history and malpractice claims experience;
- (iii) report to said board any disciplinary action which the nursing home takes against any physician providing medical care in the nursing home; the nursing home shall report to the board any disciplinary action within thirty days of the occurrence of the reportable action; the report shall include a statement detailing the nature and circumstances of the action, its date, and the reasons for it; the nursing home shall file an annual disciplinary summary with the board; the annual disciplinary summary shall be filed no later than January thirty-first for each previous calendar year. The annual disciplinary summary shall summarize the reports submitted for the previous calendar year; the annual disciplinary summary shall be sent by certified or registered mail, and it shall be under oath; if the nursing home submitted no reports for the previous calendar year, then the annual disciplinary summary shall state that no reports were required; and
- (iv) simultaneously send to said board a copy of any report sent to the department of public health pursuant to the provisions of sections seventy-one and seventy-two, whenever any such report indicates incompetency of a physician or other conduct by a physician that seriously affects a nursing home patient's health and safety.

The types of incidents reported under this section, shall be jointly determined by the Department of Public Health and the Board of Registration in Medicine and may be set forth in regulations promulgated by the board.

M.G.L. c. 111, § 204: Confidentiality of proceedings, reports and records of a medical peer review committee

Exceptions and immunity to the confidentiality of proceedings, reports and records of a medical peer review committee

- § 204 (a) Except as otherwise provided in this section, the proceedings, reports and records of a medical peer review committee shall be confidential and shall not be subject to subpoena or discovery, or introduced into evidence, in any judicial or administrative proceeding, except proceedings held by the boards of registration in medicine, social work, or psychology, and no person who was in attendance at a meeting of a medical peer review committee shall be permitted or required to testify in any such judicial or administrative proceeding, except proceedings held by the boards of registration in medicine, social work or psychology, as to the proceedings of such committee or as to any findings, recommendations, evaluations, opinions, deliberations or other actions of such committee or any members thereof.
- § 204 (b) Documents, incident reports or records otherwise available from original sources shall not be immune from subpoena, discovery or use in any such judicial or administrative proceeding

merely because they were presented to such committee in connection with its proceedings. Nor shall the proceedings, reports, findings and records of a medical peer review committee be immune from subpoena, discovery or use as evidence in any proceeding against a member of such committee to establish a cause of action pursuant to section eighty-five N of chapter two hundred and thirty-one; provided, however, that in no event shall the identity of any person furnishing information or opinions to the committee be disclosed without the permission of such person. Nor shall the provisions of this section apply to any investigation or administrative proceeding conducted by the boards of registration in medicine, social work or psychology.

- § 204 (c) A person who testifies before such committee or who is a member of such committee shall not be prevented from testifying as to matters known to such person independent of the committee's proceedings, provided that, except in a proceeding against a witness to establish a cause of action pursuant to section eighty-five N of chapter two hundred and thirty-one, neither the witness nor members of the committee may be questioned regarding the witness' testimony before such committee, and further provided that committee members may not be questioned in any proceeding about the identity of any person furnishing information or opinions to the committee, opinions formed by them as a result of such committee proceedings, or about the deliberations of such committee.
- § 204 (d) A court or administrative body may place reasonable restrictions on the use which may be made of the information obtained hereunder so as to maintain, so far as necessary or practicable, the confidentiality of such information.
- § 204 (e) No proceeding, report or record of a medical peer review committee obtained hereunder and disclosed in an action pursuant to section eighty-five N of chapter two hundred and thirty-one or a proceeding before an administrative body, shall be subject to subpoena or discovery, or introduced into evidence in judicial or administrative proceedings other than those proceedings or investigations specified in subsections (a) and (b).

M.G.L. c. 111, § 205: Information and records necessary to comply with risk management and quality assurance programs; confidentiality; definitions.

- § 205 (a) As used in this section the following terms shall have the following meanings:
- "Health care facility", any entity required to participate in risk management and quality assurance programs established by the board of registration in medicine.
- "Patient care assessment coordinator," a person or committee designated by a health care facility to implement and coordinate the facility's compliance with risk management and quality assurance programs established by the board of registration in medicine.
- "Risk management and quality assurance programs established by the board of registration in medicine," programs and activities undertaken pursuant to regulations promulgated by the board of registration in medicine under section two hundred and three of this chapter and sections five and five I of chapter one hundred and twelve.
- § 205 (b) Information and records which are necessary to comply with risk management and
 quality assurance programs established by the board of registration in medicine and which are
 necessary to the work product of medical peer review committees, including incident reports
 required to be furnished to the board of registration in medicine or any information collected or

compiled by a physician credentialing verification service operated by a society or organization of medical professionals for the purpose of providing credentialing information to health care entities shall be deemed to be proceedings, reports or records of a medical peer review committee for purposes of section two hundred and four of this chapter and may be so designated by the patient care assessment coordinator; provided, however, that such information and records so designated by the patient care assessment coordinator may be inspected, maintained and utilized by the board of registration in medicine, including but not limited to its data repository and disciplinary unit. Such information and records inspected, maintained or utilized by the board of registration in medicine shall remain confidential, and not subject to subpoena, discovery or introduction into evidence, consistent with section two hundred and four; however, such records may not remain confidential if disclosed in an adjudicatory proceeding of the board of registration in medicine, but the information and records shall be otherwise subject to the protections afforded by section two hundred and four. In no event, however, shall records of treatment maintained pursuant to section seventy of this chapter, or incident reports or records or information which are not necessary to comply with risk management and quality assurance programs established by the board of registration in medicine be deemed to be proceedings, reports or records of a medical peer review committee under this section; nor shall any person be prevented by the provisions of this section from testifying as to matters known by such person independent of risk management and quality assurance programs established by the board of registration in medicine.

M.G.L. c. 231, § 85N: Liability of licensed members of certain professional societies and committees for damages resulting from official acts.

§ 85N No member of a professional society or of a duly appointed committee thereof, or a duly appointed member of a committee of a medical staff of a licensed hospital or a health maintenance organization licensed under the provisions of chapter one hundred and seventy-six G shall be liable in a suit for damages as a result of his acts, omissions or proceedings undertaken or performed within the scope of his duties as such committee member, provided that he acts in good faith and in the reasonable belief that based on all of the facts the action or inaction on his part was warranted; nor shall an individual be liable in a suit for damages as a result of acts, omissions or proceedings undertaken or performed within the scope of his duties to a nonprofit corporation, the sole voting member of which is a professional society having as members persons who are licensed to practice medicine; provided, however, that such individual acts in good faith and in the reasonable belief that based on all of the facts the action or inaction on his part was warranted.

For the purposes of this section, "professional society" shall mean a society having as members persons who are licensed or admitted to practice in the field of law, medicine, chiropractic, optometry, psychiatry or psychology, dentistry, accounting, engineering, land surveyor, as set forth in section eighty-one D of chapter one hundred and twelve, architecture or social work.

Appendix 3

The Patient Care Assessment Regulations of the Massachusetts Board of Registration in Medicine

The Patient Care Assessment (PCA) function at the Board of Medicine is responsible for the oversight of institutional systems of quality assurance, risk management, peer review, utilization review and credentialing, known collectively as a "PCA Program." The systems comprising a health care facility's PCA program must be overseen by both physician and corporate leadership and must actively involve all health care providers and most employees at the institution.

The Board's PCA function was mandated by the Medical Malpractice Reform Act of 1986. The key provisions of the Massachusetts General Laws dealing with the Board's oversight of institutional quality assurance are M.G.L. c. 111, § 203(d) and M.G.L. c. 112, § 5. These statutes include the requirements that participation in PCA programs is a condition of both hospital and physician licensure.

Following the enactment of these statutes, the Board promulgated regulations to carry out its legal mandate of overseeing institutional quality assurance. These regulations, known as the PCA Regulations and found at 243 CMR 3.00, specify in detail the requirements broadly set out in the 1986 legislation. The regulations apply to all health care facilities, ranging from hospitals to HMOs to physicians' office settings, and include the requirement that physicians licensed in Massachusetts may not provide patient care at facilities without PCA programs.

The PCA function is unique among the nation's state licensing boards. The Board's PCA activities differ from its other, more traditional functions. The PCA Committee is not punitive or adversarial in nature; it does not discipline physicians or regulate their licensure. While its ultimate responsibility is protection of the public, the Board's PCA Committee tries to be collaborative and educational when working with health care facilities. The PCA Committee's purpose is to ensure that each health care facility does its job to assure quality; to accomplish that end, it attempts to work collegially with facilities.

The PCA Committee and Division are also unique in the confidential nature of their activities. Soon after the inception of the PCA function at the Board, the legislature passed a statute that afforded PCA information a high level of legal protection from disclosure (M.G.L. c. 111, §205). The statute provides that PCA information is confidential and not subject to subpoena, discovery or introduction into evidence.⁷⁸

Appendix 4

JCAHO Standards for Peer Review

Revision on the Intent for Medical Staff Standard MS.8.3 Relating to Peer Review (Revised 2000)

Standard M. S. 8

The medical staff has a leadership role in organization performance improvement activities designed to ensure that when the findings of the assessment process are relevant to an individuals performance, the medical staff is responsible for determining their use in Peer Review or the ongoing evaluations of a licensed independent practitioners competence, in accordance with the standards on renewing or revising clinical privileges delineated in this chapter;

Addition to the intent of MS.8 through MS. 8.4 for MS. 8.3

Members of the medical staff are involved in activities to measure, assess, and improve performance on an organization-wide basis. They are involved in conducting a properly designed peer review process that includes the following:

- Definition of those circumstances requiring peer review;
- Specification of the participants in the review process, including definition of "peer";
- Method for selecting peer review panels for specific circumstances;
- Timely frames in which peer review activities are to be conducted and the results reported;
- · Circumstances under which external peer review is required; and
- Provision for participation in the review process by the individual whose performance is being reviewed.

An effectively functioning peer review process is

- Consistent. Peer review is conducted according to defined procedures for all cases meeting the organization's definition of reviewable circumstances.
- Timely. The time frames specified in the peer review procedures are adhered to reasonably.
- Defensible. The conclusions reached through the process are supported by a rationale that specifically addresses the issues for which the peer review was conducted, including, as appropriate, reference to the literature and relevant clinical practice guidelines.
- Balanced. Minority opinions and views of the reviewee are considered and recorded.
- Useful. The results of peer review activities are considered in practitioner-specific credentialing and privileging decisions and, as appropriate, in the organization's performance improvement activities.
- Ongoing. Peer review conclusions are tracked over time, and actions based on peer review conclusions are monitored for effectiveness.

Appendix 5 Model Principles for Medical Peer Review of Physicians for Health Care Facilities

Editor's Note: The principles originally outlined in Appendix 5 of this report were updated at the May 2010 MMS House of Delegates Annual Meeting.

Massachusetts Medical Society Policy

Model Principles for Medical Peer Review of Physicians for Health Care Facilities

The following recommendations are made based on the above considerations in order to enhance:

- Quality improvement
- Credibility in the process of medical peer review of physicians for health care facilities
- Fairness and due process
- Patient access by not inappropriately removing or sanctioning physicians
- · System approaches to patient safety and quality of care

That the Massachusetts Medical Society Model Principles for Medical Peer Review of Physicians for Health Care Facilities are as follows:

- 1. Patient safety and quality of care must be the goal.
- 2. Evaluation of circumstances surrounding an adverse event in a health care facility must not only include pre-event factors, but also the contributory effects of the health care system.
- 3. All the relevant information should be obtained promptly from the subject physician. In addition, relevant information from other sources should be obtained and made available to the subject physician to the fullest extent legally permissible followed by early discussion with the subject physician to evaluate the "incident" and explore alternate course of action.
- 4. The process must be mindful and attuned to prevention and recommend appropriate individual and system changes for remediation.
- 5. Triggers that initiate a medical peer review within a health care facility should be valid, transparent and available to all member physicians and should be uniformly applied, with objective and evidence-based pre-screening, to all cases and physicians.
- 6. Physician health and impairment issues should be identified and managed by a medical peer review committee which is separate from the disciplinary process.
- 7. At a minimum, the standards set by Healthcare Quality Improvement Act of 1986 (HCQIA) for eligibility to federal immunity must be followed if a disciplinary process is engaged during professional review. These standards are the most elementary safeguards of due process in a health care facility.

Section 1112 Standards for professional review actions

- "a. In general...professional review action must be taken-
- (1) in the reasonable belief that the action was in the furtherance of quality health care,
- (2) after a reasonable effort to obtain the facts of the matter,
- (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and
- (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3)."

"Adequate notice and hearing—A health care entity is deemed to have met the adequate notice and hearing requirement of subsection (a)(3) of this section with respect to a physician if the following conditions are met (or are waived voluntarily by the physician):

- (1) Notice of proposed action
 - The physician has been given notice stating -
 - (A) (i) that a professional review action has been proposed to be taken against a physician (ii) reasons for the proposed action
 - (B) (i) that the physician has the right to request a hearing on the proposed action
 - (ii) any time limit (of not less than 30 days) within which to request such a hearing, and
 - (C) a summary of the rights in the hearing under paragraph (3).
- (2) Notice of hearing–If a hearing is requested on a timely basis under paragraph (1)(B), the physician involved must be given notice stating
 - (A) the place, time and date of the hearing, which date shall not be less than 30 days after the date of the notice, and
 - (B) a list of the witnesses (if any) expected to testify at the hearing on behalf of the professional review body.
- (3) Conduct of hearing and notice—If a hearing is requested on a timely basis under paragraph (1)(B)
 - (A) subject to subparagraph (B), the hearing shall be held (as determined by the health care entity)
 - (i) before an arbitrator mutually acceptable to the physician and the health care entity,
 - (ii) before a hearing officer who is appointed by the entity and who is not in direct economic competition with the physician involved, or
 - (iii) before a panel of individuals who are appointed by the entity and are not in direct economic competition with the physician involved;
 - (B) the right to the hearing may be forfeited if the physician fails, without good cause, to appear;
 - (C) in the hearing the physician involved has the right
 - (i) to representation by an attorney or other person of the physician's choice,
 - (ii) to have a record made of the proceedings, copies of which may be obtained by the physician upon payment of any reasonable charges associated with the preparation thereof.
 - (iii) to call, examine, and cross-examine witnesses,
 - (iv) to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law, and
 - (v) to submit a written statement at the close of the hearing; and
 - (D) upon completion of the hearing, the physician involved has the right
 - (i) to receive the written recommendation of the arbitrator, officer, or panel, including a statement of the basis for the recommendations, and
 - (ii) to receive a written decision of the health care entity, including a statement of the basis for the decision."

In addition, the notice of hearing should contain a summary of the allegations and the episodes of care under evaluation.

- 8. Summary suspension or restriction of clinical privileges may only be used to prevent "imminent danger to the health of any individual." Such summary actions must be followed by adequate notice and hearing procedures prior to becoming final.
- 9. All parties involved in the peer review process must preserve the confidentiality of all records, information and proceedings. However, all of the facts obtained for and in the peer review process shall be available to the subject physician to the fullest extent legally permissible.
- 10. A peer review committee, engaged in a formal peer review or disciplinary proceeding, may not include direct economic competitors of the subject physician or those for whom there may be bias or lack of objectivity vis-à-vis the subject physician and should include a fair representation of specialists/subspecialists from the subject physician's specialty/subspecialty whenever feasible. The subject physician shall have the right to challenge, in writing, proposed peer review committee participants for cause prior to commencement of the proceedings. Such challenge would be a part of the procedures specified in the health care facility bylaws, outside of peer review protections

- and not pa part of the actual conduct of peer review and shall not be protected by peer review statutory protections.
- 11. Physicians should rotate service on the peer review committee (round robin).
- 12. Membership on the peer review committee must be open to all physicians on the medical staff and not be restricted to one or more groups such as those practicing exclusively at a given institution, salaried physicians only or faculty physicians only.
- 13. Only physicians should be voting members of committees conducting medical peer review of physicians.
- 14. Whenever a peer review committee adequately representing the specialty/subspecialty of the subject physician cannot effectively be constituted with physicians from within the institution while excluding direct economic competitors or at the request of the subject physician, qualified external consultants or an external peer review panel through another appropriate institution authorized to conduct peer review of physicians should be appointed in accordance with the medical staff bylaws and medical peer review protection statutes.
- 15. Physicians serving on the peer review committee should receive information and where available, training, in the elements and essentials of medical peer review.
- 16. The hospital or the organization on whose behalf the peer review is done must ensure that the physicians serving on any peer review committee are provided with appropriate indemnification and insurance for peer review acts taken in good faith. The organization must also provide assistance to the committee in abiding by the requirements of HCQIA to be eligible for federal immunity.
- 17. The peer review committee of a health care facility should be guided by generally accepted clinical guidelines and established standards and practices, when available, in making their determination. When the matter before the peer review committee involves professional conduct such as an allegation of disruptive behavior, the peer review committee should be guided by applicable professional ethical principles (e.g., the MMS Code of Ethics, the AMA Principles of Medical Ethics, relevant specialty society ethical codes). Those guidelines, standards and practices must be made available in a timely manner to the subject physician before any hearing on the matter.
- 18. Clinical guidelines, standards and practices used for evaluation of quality of care should be transparent and available to the extent feasible.
- 19. Wherever feasible, structured assessment instruments and multiple reviewers should be used to increase reliability.
- 20. Where feasible, statistical analysis to compare with peers' performance must be used with appropriate case mix adjustment.
- 21. Adequate notice (no less than 30 days) should be given to the subject physician for any formal hearing or appeal.
- 22. All the pertinent information obtained by the peer review committee regarding the subject matter should be made available to the subject physician to the fullest extent legally permissible in a timely manner before the hearing.
- 23. To the extent feasible, the reviewers should evaluate the process of care given while blinded to the outcome.
- 24. Any conclusion reached or action recommended or taken should be based upon the information presented to the peer review committee and made available to the subject physician. Indefensible and vague accusations, personal bias and rumor should be given no credence and should be carefully excluded from consideration. Any conclusion reached should be defensible under a "reasonably prudent person" standard.
- 25. If the conclusion reached is that improvement is necessary, any action recommended by a health care facility should include, as an important focus, steps for remediation, as needed, for the subject physician and for the system.
- 26. The findings, recommendations and actions of the peer review committee of a health care facility should not be vague or stated in general terms, but should clearly and specifically state in writing the nature of the physician's act or omission, how it deviated from the standard of care or ethical principle, what the standard or ethical principle is and its source, and what specific step the

- physician could have taken or not taken to meet the standard of care or ethical principle. Where applicable, it must address what specific remediation, if any, is recommended for the physician and what, if any, for the system (whenever feasible, in terms that permit measurement and validation of remediation, when completed).
- 27. A process should be available to appeal any disciplinary finding of a health care facility following the hearing, and the requirements and procedures for all existing appeal mechanisms should be made available to the subject physician. An appeals process before a disinterested third party, not connected to the medical staff or the hospital, should be made available to the subject physician within statutory peer review protections. If the original action was part of a peer-review protected process, the appeal should be part of the peer-review protected process as well. (MMS House of Delegates, November 8, 2003; Amended, 5/14/10)
- 28. The Society recognizes that when a physician performs a medical peer review function he/she should render the same opinions that would pertain if he/she were the treating physician with responsibility to provide appropriate patient care. These opinions should not be rendered solely on the basis of cost containment. (MMS Council, 5/17/91; reaffirmed House of Delegates, May 7, 1999)

(HP)

MMS House of Delegates, 11/08/03 *Health Care Facilities Principles amended MMS House of Delegates, 5/08/09 Amended, MMS House of Delegates, 5/14/10

Appendix 6 AMA Policy on Peer Review⁷⁹

<u>E-9.031 – Reporting Impaired, Incompetent, or Unethical Colleagues</u>

Physicians have an ethical obligation to report impaired, incompetent, and unethical colleagues in accordance with the legal requirements in each state and assisted by the following guidelines:

Impairment. Impairment should be reported to the hospital's in-house impairment program, if available. Otherwise, either the chief of an appropriate clinical service or the chief of the hospital staff should be alerted. Reports may also be made directly to an external impaired physician program. Practicing physicians who do not have hospital privileges should be reported directly to an impaired physician program, such as those run by medical societies, when appropriate. If none of these steps would facilitate the entrance of the impaired physician into an impairment program, then the impaired physician should be reported directly to the state licensing board.

Incompetence. Initial reports of incompetence should be made to the appropriate clinical authority who would be empowered to assess the potential impact on patient welfare and to facilitate remedial action. The hospital peer review body should be notified where appropriate. Incompetence which poses an immediate threat to the health of patients should be reported directly to the state licensing board. Incompetence by physicians without a hospital affiliation should be reported to the local or state medical society and/or the state licensing or disciplinary board.

Unethical conduct. With the exception of incompetence or impairment, unethical behavior should be reported in accordance with the following guidelines:

Unethical conduct that threatens patient care or welfare should be reported to the appropriate authority for a particular clinical service. Unethical behavior which violates state licensing provisions should be reported to the state licensing board or impaired physician programs, when appropriate. Unethical conduct which violates criminal statutes must be reported to the appropriate law enforcement authorities. All other unethical conduct should be reported to the local or state medical society.

Where the inappropriate behavior of a physician continues despite the initial report(s), the reporting physician should report to a higher or additional authority. The person or body receiving the initial report should notify the reporting physician when appropriate action has been taken. Physicians who receive reports of inappropriate behavior have an ethical duty to critically and objectively evaluate the reported information and to assure that identified deficiencies are either remedied or further reported to a higher or additional authority. Anonymous reports should receive appropriate review and confidential investigation. Physicians who are under scrutiny or charge should be protected by the rules of confidentiality until such charges are proven or until the physician is exonerated. (II) Issued March 1992 based on the report "Reporting Impaired, Incompetent, or Unethical Colleagues," adopted December 1991 (J Miss St Med Assoc. 1992; 33: 176-77); Updated June 1994 and June 1996.

E-9.04 - Discipline and Medicine

Incompetence, corruption, or dishonest or unethical conduct on the part of members of the medical profession is reprehensible. In addition to posing a real or potential threat to patients, such conduct undermines the public's confidence in the profession. A physician should expose, without fear or loss of favor, incompetent or corrupt, dishonest, or unethical conduct on the part of members of the profession. Questions of such conduct should be reported and reviewed in accordance with Opinion 9.031, "Reporting Impaired, Incompetent, or Unethical Colleagues."

Violation of governmental laws may subject the physician to civil or criminal liability. Expulsion from membership is the maximum penalty that may be imposed by a medical society upon a physician who violates the ethical standards involving a breach of moral duty or principle. However, medical societies have a civic and professional obligation to report to the appropriate governmental body or state board of medical examiners credible evidence that may come to their attention involving the alleged criminal conduct of any physician relating to the practice of medicine.

Although a physician charged with allegedly illegal conduct may be acquitted or exonerated in civil or criminal proceedings, this does not discharge a medical society from its obligation to initiate a disciplinary proceeding against a member with reference to the same conduct where there is credible evidence tending to establish unethical conduct.

The Council cannot pass judgment in advance on a situation that may later come before it on appeal. The Council cannot be an attorney for a society or a member thereof and later judge in the same factual situation. The local medical society has the initial obligation of determining all the facts and whether or not disciplinary action is indicated. Questions asking for a review of a proposed course of action or an evaluation of an existing factual situation should be presented to the appropriate official of the physician's local society. (II, III, VII) Issued prior to April 1977; Updated June 1994.

E-9.05 – Due Process

The basic principles of a fair and objective hearing should always be accorded to the physician or medical student whose professional conduct is being reviewed. The fundamental aspects of a fair hearing are a listing of specific charges, adequate notice of the right of a hearing, the opportunity to be present and to rebut the evidence, and the opportunity to present a defense. These principles apply when the hearing body is a medical society tribunal, medical staff committee, or other similar body composed of peers. The composition of committees sitting in judgment of medical students, residents, or fellows should include a significant number of persons at a similar level of training.

These principles of fair play apply in all disciplinary hearings and in any other type of hearing in which the reputation, professional status, or livelihood of the physician or medical student may be negatively impacted.

All physicians and medical students are urged to observe diligently these fundamental safeguards of due process whenever they are called upon to serve on a committee which will pass judgment on a peer. All medical societies and institutions are urged to review their constitutions and bylaws and/or policies to make sure that these instruments provide for such procedural safeguards. (II, III, VII) Issued prior to April 1977; Updated June 1994.

E-9.10 - Peer Review

Medical society ethics committees, hospital credentials and utilization committees, and other forms of peer review have been long established by organized medicine to scrutinize physicians' professional conduct. At least to some extent, each of these types of peer review can be said to impinge upon the absolute professional freedom of physicians. They are, nonetheless, recognized and accepted. They are necessary, and committees performing such work act ethically as long as principles of due process (Opinion 9.05, "Due Process") are observed. They balance the physician's right to exercise medical judgment freely with the obligation to do so wisely and temperately. (II, III, VII) Issued prior to April 1977; Updated June 1994.

H-230.984 Peer Review of the Performance of Hospital Medical Staff Physicians

The AMA (1) encourages state and local medical associations to establish procedures and committees for monitoring, upon the request of the medical staff, the effectiveness of hospital medical staff peer review; and (2) supports working with the AHA and other appropriate organizations to devise methods to encourage the development of such programs. (CMS Rep. E, I-86; Reaffirmed: Sunset Report, I-96)

H-300.973 Promoting Quality Assurance, Peer Review, and Continuing Medical Education Our AMA: (1) reaffirms that it is the professional responsibility of every physician to participate in voluntary quality assurance, peer review, and continuing medical education activities; (2) to encourage hospitals and other organizations in which quality assurance, peer review, and continuing medical education activities are conducted to provide recognition to physicians who participate voluntarily; (3) to increase its efforts to make physicians aware that participation in the voluntary quality assurance and peer review functions of their hospital medical staffs and other organizations provides credit toward the AMA's Physicians' Recognition Award; and (4) to continue to study additional incentives for physicians to participate in voluntary quality assurance, peer review, and continuing medical education activities. (BOT Rep. SS, I-91; Reaffirmed: Sunset Report, I-01)

H-340.902 The New Role of PROs in Quality Improvement

Our AMA declares support for the concept of improving mainstream medical care through provider pattern analysis and quality improvement projects, rather than punitive-oriented peer review. (Res. 719, A-96; Amended: CMS Rep. 16, I-98; Reaffirmed: CMS Rep. 9, I-00)

H-375.983 Peer Review after Patrick v. Burget

(1) The AMA urges state medical associations to investigate applicable state law to determine if additional state agency supervision of peer review is needed to meet the active state supervision requirement set forth by the Supreme Court. (2) The AMA urges hospitals, medical staffs, and peer reviewers to review the guidelines for peer review conduct in Health Care Quality Improvement Act of 1986 and to observe the following guidelines: (a) In any situation where it appears that a disciplinary proceeding may be instigated against a physician that could result in the substantial loss or termination of the physician's clinical privileges, the advice and guidance of legal counsel should be sought by those persons who are involved in this phase of the peer review process. The attorney's participation should continue in preparation for the hearing including the written notice of charges, the marshaling of evidence and the facts, and the selection of witnesses. The attorney should be instructed that his role is not that of a prosecutor, but as an advisor in assuring that the proceedings are conducted fairly, bearing in mind the objectives of protecting consumers of health care and the physician involved against false or exaggerated charges. (b) The attorney advising the hearing panel and the attorney representing the physician involved should be accorded reasonable latitude in cross-examination, but acrimony should not be allowed by the hearing panel. (c) Substantial latitude should be permitted in the presentation of evidence, medical reference works and testimony, within reasonable time constraints and the discretion of the hearing panel. (d) A court reporter should be present to make a verbatim transcript of the hearing which should be available to the parties and the costs borne by the hospital or health care entity. (e) Within the discretion of the hearing panel, witnesses may be requested to testify under oath. (f) The hearing panel should consist of physicians, none of whom are direct economic competitors with the physician involved or who stand

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to gain through a recommendation or decision adverse to the physician. It is desirable that members of the hearing panel be physicians who have the respect of the medical community, but they need not be in the same specialty as the physician involved. (g) Physicians who are direct economic competitors of the physician involved may testify as witnesses, whether they are called by the physician or the hearing panel or the hospital, but a physician should not be deprived of his privileges solely on the basis of medical testimony by economic competitors. In any proceedings that result in the termination of privileges, there should be testimony from one or more physicians who are not economic competitors or who do not stand to gain economically by an adverse action, but who are knowledgeable in the treatment, patient care management and areas of medical practice or judgment upon which the adverse action is based. (h) When investigation indicates that a disciplinary proceeding is warranted for the purpose of terminating a physician's hospital privileges, he should not be permitted to resign without a finding that his termination occurred without cause. The disciplinary proceedings should be conducted by the hearing panel with the presentation of testimony and evidence, irrespective of whether the physician involved chooses not to be present. (BOT Rep. MMM, A-88; Reaffirmed: Sunset Report, I-98)

H-375.966 Peer Review Protection Under Federal Law

Our AMA supports federal legislation that will enhance protection of peer review information even if such information is shared with governmental agencies in an effort to better and more comprehensively analyze the patient safety measures and quality of healthcare measures being utilized in clinical settings. (Res. 239, A-01)

H-375.993 Confidentiality in Medical Staff Peer Review

Our AMA encourages medical staff peer review committees to consider excluding non-physicians when evaluating the professional practices of fully licensed physicians. (Sub. Res. 147, A-83; Reaffirmed: CLRPD Rep. I-93-1; Reaffirmed: BOT Rep. 8, I-01)

H-375.997 Voluntary Medical Peer Review

Our AMA advocates the following principles for voluntary medical peer review:

- (1) Medical peer review is an organized effort to evaluate and analyze medical care services delivered to patients and to assure the quality and appropriateness of these services. Peer review should exist to maintain and improve the quality of medical care.
- (2) Medical peer review should be a local process.
- (3) Physicians should be ultimately responsible for all peer review of medical care.
- (4) Physicians involved in peer review should be representatives of the medical community; participation should be structured to maximize the involvement of the medical community. Any peer review process should provide for consideration of the views of individual physicians or groups of physicians or institutions under review.
- (5) Peer review evaluations should be based on appropriateness, medical necessity and efficiency of services to assure quality medical care.
- (6) Any system of medical peer review should have established procedures.
- (7) Peer review of medical practice and the patterns of medical practice of individual physicians, groups of physicians, and physicians within institutions should be an ongoing process of assessment and evaluation.
- (8) Peer review should be an educational process for physicians to assure quality medical services.
- (9) Any peer review process should protect the confidentiality of medical information obtained and used in conducting peer review. (CMS Rep. A, I-81; Reaffirmed: CLRPD Rep. F, I-91; Reaffirmation I-98; Reaffirmed: BOT Rep. 8, I-01)

American Medical Association

Physicians dedicated to the health of America

515 North State Street Chicago, Illinois 60610 312 464-5000 312 464-4184 Fax



Memo to: Executive Directors

State Medical Associations

National Medical Specialty Societies

Hospital Medical Staff Presidents and Chiefs of Staff

From: Timothy T. Flaherty, MD, Chair, Board of Trustees

Michael D. Maves, MD, MBA, Executive Vice Presider

Date: March 1, 2002

Subject: Compliance with the Health Care Quality Improvement Act (HCQIA)

The American Medical Association supports peer review by physicians and protection of peer review documents and proceedings. The AMA also discourages involvement in peer review proceedings by physician panel members who are economic competitors of the peer reviewed physician and discourages medical testimony by economic competitors when the proceedings may result in termination of the affected physicians privileges, AMA Policy H.375-983. (Attachment)

Peer review by physicians is essential to ensure and improve quality care for patients. It should be performed by physicians. However, absent immunity, some physicians may be unwilling to participate in this responsibility of their profession. The Health Care Quality Improvement Act of 1986 (HCQIA) was enacted to encourage physicians to participate in peer review by providing limited immunity from money damages. To qualify for immunity, peer review action must meet specific criteria. (Attachment)

The potential for abuse of peer review exists. Personal agendas, competition or other reasons unrelated to quality care must not be the motivation for peer review actions. Peer review that is not fair or objective can undermine patient care, patient access as well as a physician's reputation. Failure to adhere to a fair peer review process can erode public confidence in the ability of the medical profession to adequately monitor itself.

In order to ensure quality patient care and to assure fairness to all physicians, the AMA urges all medical staffs to adopt and implement medical staff bylaws that comply with AMA policy and HCQIA.

We hope that physicians continue to remain tireless advocates for their patients by continuing to pursue high quality care. By ensuring that medical staff bylaws conform with HCQIA requirements and AMA policy, patients, the public and physicians will all benefit.

Attachments

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- 50 However, it should be noted that based upon a suggestion in an Appeals Court case, <u>Swatch v. Treat.</u> 41 Mass. App. Ct. 559, 562 (1996), two recent Massachusetts trial courts decisions have distinguished between corrective or educational peer review proceedings and punitive peer review proceedings which accorded the subject physician due process rights. <u>Pardo v. the General Hospital Corp.</u> 2001 WL 1174252 (Mass. Super., 2001); <u>Ayash v. Dana Farber Cancer Inst.</u>, 1998 WL 77854 (Mass. Super.,1998). In these two rulings, the trial judges permitted discovery of materials from a "punitive" peer review process on the basis that such proceedings were not within the scope of the privilege provided for peer review committees by Massachusetts law. While this interpretation of the Massachusetts peer review law is contrary to the plain language of the statute and legislative intent, these rulings have not been corrected by an appellate court to date.
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