January 31, 2003

Harold J. Bressler, Esquire
General Counsel
Joint Commission on Accreditation
Of Healthcare Organizations
One Renaissance Blvd.
Oakbrook Terrace, IL 60181

Dear Hal:

Thank you for your letter dated December 18, 2002 inviting the American Health Lawyers Association's (Health Lawyers) input on the Medical Staff Chapter Standards. Enclosed is a response drafted by the leadership of the Credentialling & Peer Review (CPR) Practice Group. The leaders of the CPR Practice Group are Dan Mulholland of Horty Springer & Mattern; Sherry A. Fabina-Abney of Ice Miller Donadio & Ryan; Ann O'Connell of McDonough Holland & Allen; Brenda Strama of Vinson & Elkins; and Michael Cassidy of Tucker Arensberg.

The CPR Practice Group is composed of volunteer members who provide advice and counsel on credentialling and peer review issues in all types of healthcare settings, including issues of medical staff and physician relations; peer review; privileging; selection and de-selection of practitioners; allied health practitioners; and medical staff bylaws.

The attached response is the response of the CPR Practice Group's leadership. It should not be construed as the "position" of Health Lawyers for the reasons detailed below.

Health Lawyers is the nation's largest educational organization devoted to legal issues in the healthcare field. With approximately 9,200 members, Health Lawyers provides resources to address the issues facing its members who practice in law firms, government, in-house settings and academia, and representing clients from the entire industry spectrum: physicians, hospitals and health systems, health maintenance organizations, health insurers, managed-care companies, long-term care facilities, home health agencies, durable medical equipment suppliers and consumers. Hence, Health Lawyers members provide leadership, legal representation and corporate and regulatory counsel to virtually every sector of the healthcare industry.

Health Lawyers' mission is to provide a forum for interaction and information exchange to enable its members to serve their clients more effectively; to produce the highest quality non-partisan educational programs, products and services concerning health law issues; and to serve as a resource on various legal issues related to the delivery of healthcare in the United States. Health

Lawyers is a non-profit, tax-exempt educational association governed by a board of directors.

The attached comments do not represent the “position” of Health Lawyers with respect to the Joint Commission’s new Medical Staff Chapter Standards. The Association does not take positions on policy matters or on accreditation issues. Health Lawyers purposefully does not engage in advocacy activities. However, the Association’s mission does include a directive to act as a public resource on various healthcare legal issues. It is in this capacity that I forwarded your letter to the CPR leadership. The purpose of the attached comments is not to advocate for any particular position or outcome with the Joint Commission, but simply to give you the benefit of our CPR Practice Group leadership’s experience and knowledge in this field. Health Lawyers wants to be a resource to help the Joint Commission produce the best standards possible.

Thank you for thinking of Health Lawyers, and I hope you find the CPR Practice Group leadership’ comments helpful.

Sincerely,

Peter M. Leibold
Executive Vice President and CEO

ADDITIONAL COMMENTS ON JCAHO REVISED MEDICAL STAFF STANDARD

The JCAHO should be commended for its efforts to simplify the wording, improve the understandability of the standards, and to begin to move away from criteria that have often lead to surveyor variation. The following comments are offered in addition to the responses to the field review questionnaire.

1. Status of the Medical Staff

The title and text of the Standards refers to the "organized" medical staff without ever explaining the meaning or purpose of the term, "organized." If it is meant to imply that the medical staff needs to be "organized" or structured in a particular way to perform its functions, it would seem like mere surplusage, since Standard MS.1 describes the structural requirements in sufficient detail. If, on the other hand, it is intended to imply that the medical staff is a "self-governing" organization which has a separate existence from the hospital, perhaps to advance the personal interests of its members in the manner of a labor union, such a view would be legally incorrect. As recent case law has made clear, the medical staff is an integral part of the hospital, having been created by the governing board. Exeter Hospital Medical Staff v. Board of Trustees of Exeter Hospital, 810 A.2d 53 (NH 2002). Therefore, it would suffice to simply refer to "the medical staff" rather than "the organized medical staff" throughout the standard and also eliminate confusing references to "self-governance."

2. Role of the Medical Staff

Rationale MS.1 states that the "organized medical staff has overall responsibility for the quality of the professional services provided, including a single level of care, and is accountable for that responsibility." The opening paragraph under medical structure states that the primary function of the organized medical staff is to provide oversight for the quality of care. It is far better to state this in terms of oversight rather than saying that the staff is "responsible" for the quality. Saying that the organized medical staff is responsible for quality could invite malpractice suits against all members of the medical staff on the basis that they were collectively responsible for all care rendered in the hospital. See Corleto v. Shore Memorial Hospital, 350 A.2d 534 (N.J. Super 1975). There are other references throughout the document that could be read to create a basis for collective responsibility, which also should be changed to clarify that the staffs role involves "oversight' and not ultimate responsibility for the quality of care rendered by every member of the staff.

3. Governance Documents

Rationale for MS.1.1 states that the medical staff creates a written set of documents, and that "these documents are called bylaws." The section goes on to state that the organized medical staff may create additional governance documents such as policies, procedures, protocols, rules and regulations. The sentence stating that "these documents are called bylaws," should be revised to make it absolutely clear that the entire set of documents are not "called

bylaws," and that organizations may choose to put certain things in the "additional governance documents." The standard should also clarify that medical staff members and others practicing at the hospital are subject to bylaws, policies and procedures adopted by the governing board.

On page 6, under "Corrective Actions," the standards state that the medical staff bylaws include a list of things, including automatic and summary suspensions, and fair hearing procedures. Since many organizations have credentialing policies, cross-referenced in the bylaws, that contain these provisions, it should be made clear that it is acceptable for such procedures to be contained in the "additional governance documents" referenced above.

The elements of performance under rationale for MS.1.1 at the top of page 7, states that the medical staff bylaws require that Medical Staff Executive Committee defines the qualifications for appointment to membership of the medical staff in the bylaws. Often, the qualifications are set forth in the credentialing policy, and the standards should allow for such flexibility.

Finally, Standard MS.1.1.2 should allow the governing board to unilaterally amend the medical staff bylaws, after consultation with the Medical Staff Executive Committee, if the amendment is necessary to conform the medical staff bylaws to: (a) applicable statutes, regulations or judicial decisions, (b) the standards of the JCAHO, or (c) the bylaws of the governing board. This would be in line with the legal status of the medical staff (see above) and assure that hospitals could come into compliance with accreditation and regulatory standards in situations where the medical staff was either unwilling or unable to adopt necessary amendments in a timely manner. It would also allow the governing board to carry out its fiduciary duty to assure that the hospital is in compliance with applicable regulatory and accreditation requirements, which can be thwarted if the medical staff fails to approve needed amendments.

4. Medical Staff Appointment

Throughout the document, the terminology "appointment to membership" is used. The JCAHO should select one term, either membership or appointment, and use that term consistently. The terminology "appointment to membership" is not generally used.

There is a also a statement within Standard MS.6.4, Elements of Performance (number 5 at the top of page 22) that states: "Membership is granted by the medical staff and the organization." This is legally incorrect, since pursuant to the licensure laws of every state, only the hospital board has the ultimate legal authority to grant membership. It is also unwise from an antitrust perspective to suggest that membership on the medical staff is granted by the medical staff. This reference ought to be changed to state that membership is granted by the governing board, after considering the recommendation of the Executive Committee.

5. Medical Staff Executive Committee

In several places, the Standards state that the medical staff can delegate authority to the Medical Staff Executive Committee to carry out medical staff responsibilities and to act on behalf of the organized medical staff between medical staff meetings. This is an anachronistic. Many organizations have dramatically reduced the number of full medical staff meetings to one annual meeting, with the authority for mail ballots to deal with bylaws amendments or other pressing issues in the interim.

Again, from an antitrust perspective, it is best not to create the perception that the entire medical staff is the responsible entity. Stating that the Medical Staff Executive Committee only acts pursuant to delegated authority could expose the entire staff (and the members of the Medical Staff Executive Committee) to increased risk of individual liability in suits by practitioners who subject to adverse recommendations.

Hospitals should have the flexibility to define a core group of medical staff leaders who actually carry out most of the responsibilities of the Medical Staff and are empowered to carry out their responsibilities. Reinforcing the perception that all actions flow from the entire organized medical staff as a democracy, in effect, perpetuates an organizational structure that does not work and can actually impede compliance with accreditation requirements and efforts to improve the quality of care. In some organizations, the inability to get the entire medical staff to vote favorably on any important quality improvement and performance improvement activities that the JCAHO has been advocating for a number of years could be the biggest impediment to achieving most of the JCAHO's performance improvement goals. In most hospitals, there is a core group of physicians who, in addition to being good clinicians, have the aptitude for leadership. Continuing the concept that everything must be voted on by the organized medical staff functioning as a democracy is a significant impediment to performance improvement activities taken by the leaders of the staff.

We would therefore suggest that the Standards should be amended to either:

(1) remove the language that appears to create a requirement that everything must be voted upon by the entire medical staff (and that the Medical Staff Executive Committee is only acting on behalf of the entire staff between meetings); or

(2) create a special "opt-out" of these provisions, to allow hospitals to empower leadership groups such as the Medical Staff Executive Committee to develop policies, procedures, protocols, and other documents subject only to notice and comment by the entire staff.

6. Credentialing

Item #25 on page 18 states: "Decisions on membership and granting of privileges must consider criteria that are directly related to the quality of health care. If privileging criteria are used that are unrelated to quality of care or professional competence, evidence exist that the impact of resulting decisions on the quality of care is evaluated." It should be made clear that this section does not prohibit utilizing "such other eligibility criteria as the governing board may determine" such as declining to provide an application to someone seeking privileges in an area covered by exclusive contract; declining to provide an application in an area determined by a medical staff development plan pursuant to which there is not a current need in the community for that specialty; or a board's determination not to provide an application to an individual with a financial conflict of interest. See, e.g., Hershey, "A Different Perspective on Quality" 17 American Journal of Medical Quality 242 (2002). The governing board clearly has the legal authority to make such decisions. Mahan v. Avera St. Luke's, 621 N.W.2d 150 (S.D. 2001). Such policy decisions should not be prohibited by accreditation standards. There should be a sentence stating that nothing in the JCAHO standards should be construed as limiting the ability of the governing board, in furtherance of its fiduciary responsibilities, to make determinations on eligibility for medical staff membership.

On page 15,, the term "letters" is used with reference to the documentation required for credentialing. Sometimes, the information provided regarding an applicant's training, experience and competence comes in the form of an evaluation form as opposed to a letter, so evaluation forms should be referenced as well.

On page 19, the final paragraph in the highlighted area under "Ability to Perform Privileges Requested" contains a statement that in instances where there is doubt about an applicant's ability to perform privileges, an evaluation may be requested and, "the request for an evaluation rests with the organized medical staff." On the next page, under rationale for MS.6.3, the final sentence at the bottom of the page states that the connection with reappointment, "the request for such an evaluation rests with the Executive Committee of the organized medical staff." It is preferable to vest the Executive Committee with the responsibility for requesting evaluations of an applicant's ability to perform privileges, not to create the impression that it is the entire staff that plays a role in this area. This not only creates issues of confidentiality, but also antitrust risk, if the impression is created that it is the entire staff that does this.

In several places, the JCAHO has used the word "challenge" in connection with licensure or registration, a term that is also used in the current standards. This is a term that has ambiguous legal significance and is not as precise as "investigation" or "action."

The requirement that the credentialing process be completed within a specified time frame should be a guideline rather than a firm requirement. It is often enough impossible to meet these timeframes (and if very long timeframes are established as an alternative, one could

expect all credentialing activities to slow to that pace). A more reasonable standard would be to require good cause to be articulated to the applicant if the specified time frame is not able to be met.

7. Hearings and Appeals

The removal of the fair hearing and appeal standard is appropriate, because such issues are generally subject to state hospital licensing regulations, case law in each state, and the safe harbor for fair procedures provided in the Health Care Quality Improvement Act. In some cases, counsel for a physician who is subject to an adverse recommendation have attempted to use language in the JCAHO standards to argue against the ability of a hospital to take an adverse action. The JCAHO standards should not give rise to claims by attorneys for physicians who are subject to peer review, too, which, in essence, create a "private right of action."

8. Temporary Privileges

The JCAHO determination in Proposed Standard MS.6.8 that it is not permissible to "extend" an appointment when all of the steps of a reappointment proceeding have not been completed – coupled with a limited allowance for "temporary privileges" – unnecessarily burdens the Medical Staff reappointment processes. The exception for an "important patient care need" is often unworkable and inadequate. Moreover, there is no reason to believe that these limitations are necessary or actually contribute to quality of care. Among the specific problems:

- § If there is another member of the staff who has the necessary privileges, patient care must be transferred – i.e., disrupting the physician/patient relationship.
- § Once at least one member is identified as having the necessary privileges, other similarly-situated physicians are foreclosed from receiving a comparable dispensation.
- § This can jeopardize back-up call arrangements, as well.
- § There is little logic to a determination that allowing one physician to have temporary privileges (to fulfill a need) is any safer than allowing several physicians to have such privileges.
- § Temporary privileges are available to practitioners who are not yet known to the Medical Staff (i.e., applicants awaiting processing of privileges). There is little logic to a determination that similar accommodation cannot be made for practitioners who are established and known to the Medical Staff.

9. HIPAA Privacy Rule

The JCAHO may wish to add a section reiterating the position taken by HHS that the hospital and all members of its medical staff are part of an "organized health care arrangement" for the purposes of the federal privacy regulations that will go into effect in April. The standards should also require medical staff cooperation with hospital privacy compliance efforts.