



Notes

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We have created a 60 pp. HIPAA Privacy Compliance Protocol for Physician Practices which is intended to help physicians cope with the privacy rules. It is not a book of forms or a template. It is a document which is intended to help physicians develop their own plans. It is available for \$75 to clients and \$125 PREPAID, to non-clients. Enforcement can begin April 14, 2003. If you want a copy let us know. We can send it electronically, too.

The Organized Medical Staff: Should Anyone Care Anymore?

Every hospital has an organized medical staff, but of what value is this organizational construct in the current environment? Given the new world order of quality improvement, patient safety, the malpractice crisis, and the multiple demands physicians struggle to accommodate on a daily basis, it is time to reconsider the role of the medical staff. This AGG Note (1) looks at the legal basis for the medical staff's role; (2) considers typical medical staff bylaws contents; and (3) addresses some of today's hottest potatoes between medical staffs and boards, all in light of the new quality era. Based on my more than 25 years of working with medical staffs on these issues, and reflecting themes around CPGs which I have propounded both in earlier AGG Notes (vol. 11, no.1) and work for the AMA (See, "Resources" below), I then make the case that while the medical staff is a vital component of the hospital's mission, still, both in the bylaws and in its functions, today's staff can be revitalized in ways that can be far more meaningful to physicians and far more likely to propel quality.

From the IOM's now four reports on health care quality in America, to the Leapfrog Group's push for computerized physician order entry, channeled referrals to centers of excellence and use of hospitalists, to new responses to the malpractice insurance crisis, the public policy lens has refocused on hospitals. For hospitals to succeed in meeting market and policy demands for improved quality they must rely on the physician members of their medical staffs. Yet, in many ways, the

traditional trappings of hospital-medical staff relations call into question the continuing vitality of this essential relationship.

The physicians on the staff represent disparate economic home bases -- from direct employment with the hospital or system, to recently merged megagroups, to small and solo practices. Often in competition with each other, these clinicians come together in common cause only around their use of the hospital's resources to meet their

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own needs in treating their patients. Medical staff participation in critical hospital quality activities is, in many ways, at an all time low. Many physicians do not perceive that the medical staff organization, its role or activities offers anything meaningful to them. Medical staffs, hospital boards and administration are at loggerheads throughout the country over issues which are absorbing to them but tangential to the real goals of an organized medical staff.

Legal Mandates

A hospital has no business to conduct without the physicians who make up its medical staff, order its services and refer to the other physicians on the staff. Nothing happens in the hospital without a physician order somewhere at the genesis of the activity. The theory behind the role of the organized staff is that the lay board of directors, charged with the legal and fiduciary responsibility to assure the quality of care rendered in the hospital, is neither trained nor competent to judge quality of care and clinical competence of the physicians. The medical staff, therefore, is delegated the responsibility to advise the board on these matters, while the board retains the legal authority to make all the ultimate decisions.

To implement this advisory function there must be a system which entails rules and procedures. This need is recognized in three primary sources of law: (1) the Medicare Conditions of Participation for hospitals; (2) the Joint Commission on Health Care Organizations accreditation standards which are drawn into the law by virtue of hospitals seeking "deemed status" where their JCAHO accreditation serves to qualify them for Medicare; and (3) some state hospital licensing regulations – the threshold for operating a hospital within a state's borders.

The Medicare Conditions and the JCAHO standards both require that the medical staff have bylaws which establish the mechanisms by

which they will accomplish their tasks. Some state hospital licensing regulations impose similar requirements. They do not direct how the staff is to operate, other than in general principles pertaining to fairness and involvement of the staff in matters at the board level which affect them; but they do establish the overall responsibilities to review applicants, members and the quality of care rendered within the institution.

Even as the JCAHO has changed its accreditation standards to be less prescriptive and more oriented around performance improvement, the traditional chapters on governance and medical staffs have changed relatively little. On the other hand, as far as the JCAHO is concerned, the leadership of the medical staff is expected to play a significant role in the overall leadership of the organization in support of its quality mission.

Another legal influence on medical staff activities is the Health Care Quality Improvement Act (HCQIA), which provides immunity from antitrust liability for those who engage in quality review through professional review actions. In order to be eligible for the protections, though, the processes used to make judgments that affect membership and/or clinical privileges must meet certain procedural safeguards. As a result, the HCQIA drives due process and to which types of activities such procedures pertain. As part of this regulatory scheme, the National Practitioner Data Bank (NPDB) was established to provide a clearinghouse of quality information which hospitals are expected to consult to be sure the physicians under review do not have licensure, peer review or malpractice problems which have been reported.

Physicians conducting reviews are often so fearful of the potential implications of a Data Bank report, that they struggle to fashion corrective actions which avoid reporting. For example, a mere documented concern in the credentials file, terms of probation, a letter of

reprimand, mandated consultation with another practitioner, profiling of the practitioner on a more intense basis, mandated continuing education and even a required psychiatric examination would not be reportable to the Data Bank unless the physician's membership or privileges could not be exercised until those actions took place. On the other hand, mandated co-privileges with another practitioner, mandated consultation to exercise privileges and suspension of privileges pending psychiatric examination are all reportable. In addition, the demands of the formal process required to claim the immunity protection also have a chilling effect on the medical staff's will to act. As a result, many medical staffs acknowledge in the bylaws the directives of the HCQIA but try to avoid its harshest impacts except in the most egregious circumstances. This brings us to what bylaws typically take into account.

Typical Bylaws Mindsets

Over the last twenty-five years two approaches to bylaws drafting have emerged: (1) the typical version where a single document contains within it all substantive matters including the fair hearing plan; and (2) an approach popularized by the Horthy, Springer and Mattern law firm which uses a multi-volume approach – one document is the actual bylaws, another the credentialing process, another the organizational structure (e.g., committees, departments), another the fair hearing plan, and yet another the rules and regulations. The theory here is that the documents not labeled “bylaws” are policies which are more easily amended. Given the essence of what the staff does, why would you want to amend these documents easily? We believe the medical staff bylaws, in the totality of what they establish for the medical staff and hospital, are the constitution of the medical staff and therefore ought not be amended willy-nilly with changing fashions. Other bylaws which manifest a particular orientation are those where the Credentials Committee reports directly to the Board and not

to the Executive Committee, where the Board must approve officers, elected department chairs, and all committee chairs, where the Credentials Committee consists of the past five presidents of the medical staff --- these all reflect a concern that the medical staff is unable to manage its own affairs. This is not to say that medical staffs do not act out. They do, and they have been known to get into pitched battle with the administration and board over issues which hardly merit the tenacity with which they are expounded. But the control features just described tend to reflect a belief that they will misbehave even when there is neither evidence nor history to support that belief.

Typical Bylaws Contents

The bylaws usually address the basic relationship between the board and the staff, the purposes of the staff, and provide, as the JCAHO requires, that neither party may unilaterally amend them. The qualifications for membership (e.g., board certification, location within the community, ability to respond to an emergency within a specified timeframe) are set forth along with licensure, malpractice insurance, continuing education and other fundamental requirements. The extent to which the medical staff absorbs anti-referral laws and other ethical proscriptions into the bylaws also varies.

Categories of the staff are set forth. The categories distinguish primarily the prerogatives and responsibilities of the members, so they balance citizenship rights (voting in the general meetings, committees and departments, to serving in leadership positions) with obligations (e.g., paying dues, treating indigents in the emergency department, taking emergency on call responsibilities, proctoring other physicians). There was a time when staffs had many categories. Over time, simplicity has become the hallmark of usable bylaws. So the numbers of categories have diminished. Still, whether the Courtesy Staff category should be allowed, and if so, how few interactions qualify them for their limited roles; whether Consulting Staff should be allowed to vote

at all and whether Honorary Staff should pay dues are typical concerns. As the hospital world has changed, though, these traditional issues have been joined by new ones: should employed hospitalists vote? Should primary care physicians who never set foot in the hospital be medical staff members when the medical staff cannot vouch for their quality at all? Can physicians who are employed by the hospital or one of its affiliates serve as real representatives of the medical staff on staff committees? These questions define the culture of the staff.

There are many other features of bylaws around which cultural decisions can be made ranging from the burdens of proof in the fair hearing process, to how nominations for staff officers get made, to whether department chairs are elected or contracted with the hospital. The context of a medical staff is nuanced, but the nuances frequently represent "French general" provisions - the staff remembers a bad experience and drafts the bylaws to prevent its recurrence. These matters can present major political dilemmas in the staff, but they rarely are about the real work of the staff - to safeguard the quality of care in the institution.

Current Medical Staff Hot Potatoes

(1) *Economic Credentialing*: This term has come into fashion to describe a variety of hospital behaviors which take into account in membership and privileging decisions the economic impacts of the physician's care. It used to be that this term was used primarily with regard to membership decisions that turned on the economic efficiency of the physician - whether his patients typically stayed longer than the DRG - contemplated average, for example. Today this term is used to describe decisions to reject medical staff applicants, or candidates for leadership positions, because they are invested in a 'competing' facility whether a specialty hospital, an ambulatory surgery center, or an imaging center. Not only is the investment apparently a concern, I have seen physicians asked to complete highly detailed disclosure documents extending beyond their

ownership to any financial relationship they or a family member may have with a 'competing' institution. I believe this is nothing more than a tacit demand for referrals since the investment itself obviously has no implications to the inquiring hospital. It is the expected referral to the competing entity which raises concerns. Under Pennsylvania hospital licensing regulations I believe that credentialing decisions made on these bases would be illegal under a provision adopted in 1974 which prohibits making a credentialing decision on the basis of any criterion lacking in professional or ethical justification, including affiliation with a prepaid health care organization. (28 Pa Code §107.3(c))

Other related activities include loyalty oaths -- a pledge not to sell a practice or invest in a competitive entity without offering the hospital a right of first refusal, requirements to dedicate a portion of the practice to the institution, requiring as a condition of heart station interpretation rights, for example, that the cardiologists refrain from offering the same studies in their own practices. These are policies I have seen personally and I believe they are all inappropriate.

There is, in fact, a completely legitimate basis to evaluate certain referral patterns of physicians. There is a real quality issue associated with the volume of services that certain critical physicians will perform in the hospital. Over and over again, those concerned with quality have learned that the best way to assure good outcomes, particularly for high risk surgical procedures, is for a hospital to have the opportunity to do many of them, repetitiously, involving the same teams of practitioners - nurses, physicians, operating room technicians - who are used to dealing with each other in a team context. This is the premise behind the Leapfrog Group's recommendation of evidence based hospital referral. It is entirely appropriate for a hospital to determine that for certain critical services it will only award clinical privileges to those physicians who perform a sufficient volume of procedures there to assure them that (1) not only will the team approach to quality be provided, but

also (2) that the number of procedures performed is sufficient to be able to effectively monitor the physician's quality over time, and thereby assure the capacity of the hospital resources to meet patients' needs for those specific services. If the medical staff has insufficient data to be assured that clinical competence is present, the hospital would have to seek quality relevant data about the practitioner from other institutions. Then there is no guarantee the requisite clinical information will be made available, since the other institution will have its own constraints on sharing patient and/or peer review data.

The OIG has called for comments on the ways in which these economic credentialing practices may implicate the anti-kickback statute. We have responded with an 11pp. letter stating our views. Now we will see where the chips fall.

(2) *EMTALA On Call Obligations:* Increasingly physicians are wary about responding to requests to treat patients in the emergency department, since to do so establishes a doctor – patient relationship with all the attendant liability issues, as well as the payment concerns when patients are indigent or uninsured. Some physicians actively seek to be on the on-call rotational schedule for the emergency department. Others try to avoid it. Some medical staffs mandate participation. Some leave it to departmental decisions.

The actual obligation to screen, stabilize and treat under EMTALA is a hospital obligation. Once a physician is on the call schedule, though, failure to respond appropriately to a request to attend a patient can trigger a \$50,000 civil money penalty. There are quality issues in who is obligated to or permitted to respond to emergency patient needs. How hospitals meet their obligation and the extent to which they impose these burdens on physicians contributes to other tensions both between the medical staff and the administration as well as among medical staff members, especially when some take coverage and others do not.

(3) *Cross-Department privileging:* Here it is the

advances in medicine and technology which create tensions within the medical staff. Vascular centers of excellence, women's centers, and cancer centers are all examples of ways in which hospitals seek to consolidate multidisciplinary services. Sometimes the physicians seek to do so for their own reasons. Where physicians of different specialties seek privileges to provide the same services, many issues can arise. How these get mediated so the overall strategic goals are accomplished without threatening the subtle fabric of referrals which define how medical staff members interrelate can be a significant challenge since each department views their specialty's training as the most appropriate for those privileges. For example, when the cardiologists, the radiologists, the vascular surgeons and the general surgeons all start crossing each other's borders, how will peace be maintained in the valley?

(4) *Using NPPs:* Increasingly, physicians are finding that using non-physician practitioners (NPPs) as both physician extenders and substitutes can substantially enhance the time they spend with their patients in their highest and best use. Some of these clinicians are recognized by payors, including Medicare, for direct billing. In addition, Medicare has recently significantly liberalized the way NPPs and physicians can work together to provide patient visits in the hospital when they are part of the same group practice. This phenomenon will increase the pressure on staffs to review and credential these individuals so they can help the physicians. More difficult issues arise when the hospital employs these NPPs and the staff has to either move them into the overall privileging process or rely on the hospital's contracts and job descriptions to control the quality of care they provide.

(5) *Board-Staff Communication:* Here is where the rubber hits the road in terms of how much the medical staff is likely to be creative about the new quality environment. How and about what the board (and administration) communicates with the physicians colors their entire relationship with the medical staff and in many places has become a flashpoint in medical staff-hospital relations.

Hospitals very often are happy to let the physicians tend to the credentialing/privileging activities, but involve them in no other major strategic initiatives until most of the substantive decisions have been made. In some ways, medical staffs have contributed to this counterproductive dynamic by their insistence on isolated self-governance and autonomy. Medical staffs do not have a strong track record with regard to collaborative decision making, but they have not been given many opportunities in this realm, either.

Sometimes the board or administration adequately anticipates those issues on which there is likely to be real medical staff restiveness because their economic oxen are most obviously going to be gored – as where the board decides to take an otherwise open department and make it subject to an exclusive contract. But very often there are critical issues around strategic planning, manpower planning, budgeting, capital expenditures (particularly on information technology) where the hospital seeks major change in its clinical culture but the physicians are the last to know what is being planned. If quality is really to improve in hospitals, the dynamics between the Board and administration and the staff will have to change to a far more explicitly collaborative process.

Rethinking the Process

To drive quality in the hospital the physicians must be engaged. Nothing happens in a hospital without a physician order. Without the willing hearts and minds of the physicians, real progress in quality will remain elusive. Yet, physicians are staggering under the crushing weight of significant administrative burdens imposed on them by regulation and payer contractual demands. To get them to a point where they can actively propel quality in the hospital, the hospital will have to help them standardize what they do, simplify the demands imposed on them, and make their environment more clinically relevant to the way they think and treat. When this happens, physicians cannot help but recapture time they lose now in awful inefficiencies. This time can be spent

in developing stronger, healing relationships with their patients, and in engaging in activities at the hospital which have meaning for them, including medical staff activities.

In order to bring these principles to bear, it is important to articulate a continuum of medical staff involvement -- where it is imperative, or important, or useful or not a priority to engage meaningful medical staff input. I have articulated such a continuum and continue to refine these ideas (See “Resources”, below). Each institution should have its own list which is collaboratively developed and articulated. Once this happens, clear principles of engagement between the staff and hospital can change the context in significant ways.

1. When physicians are essential to implementation of a hospital initiative, the medical staff should be involved at the earliest stages of the discussion and planning.
 2. To involve the staff it is critical to identify the real leaders, who often are the physicians with the right titles – Department Chair, President, etc – but sometimes other physicians are the real spiritual leaders of the medical staff culture.
 3. For any collaboration to work there must be trust between the parties – often where trust has broken down already. Here the principle is to win trust back. To do that the medical staff and hospital representatives to the process must do what they say, and say what they do, consistently, over time.
 4. For trust to develop, there must be open, frequent, candid communication including on negative and difficult issues. At the same time, the process should have appropriate confidentiality safeguards in place, recognizing the sensitive nature of the matters at issue where the medical staff moves into areas beyond traditional credentialing and privileging.
 5. The players in the process must be willing to be held accountable for their participation. That means that when the process comes to a decision, the
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decision should be supported by the participants even when they disagree with it. Dissent is fine, but if the mechanism operates fairly, then a properly concluded decision involving the medical staff and the administration and/or board should not be undermined and second guessed out of pique. To agree to collaborate means no one wins all the time.

6. Accountability also means that if a representative is to participate in meetings or discussions, that person must make the commitment and fulfill the obligation to be there. Physicians are notoriously bad about this on the grounds that the patients come first. To have a quality-driven hospital where the patients can come first safely, the physicians should make arrangements for coverage when they are involved in important medical staff activities. Similarly if the hospital representatives do not show up consistently nor adhere to the same principles, they simply show the medical staff the process doesn't matter – also a common and counter-productive approach.

7. Documenting the process eliminates disagreements over what was understood, solidifies the nature of the undertaking, and speaks to other stakeholders, internal and external, who will want to understand what the hospital-medical staff relationship is about.

Whether a new collaborative process is documented in the bylaws is not really the point. The real issue is to identify those matters on which the medical staff ought to be involved if the goals of the hospital with regard to quality and the needs of the physicians on the same points will be met.

Simplify, Standardize, Make Clinically Relevant

To simplify physicians' lives, improve quality and give them back time, one of the most significant boons may be the use of clinical practice guidelines (CPGs) collaboratively selected and used both in the physician office and the hospital setting.

Without elaborating on the advantages to physicians in their private practices from implementing CPGs as the foundation for much of what they do and how they organize their work (see "Resources" below), administratively and clinically, CPGs can also play some new roles in the work of the medical staff.

1. Much of the debate over cross-department privileging turns on who is competent to perform what privileges. JCAHO requires uniformity in quality throughout the institution. In addition, in awarding new privileges, it has long been the practice to have other physicians proctor the new entrants. Yet, the proctors rarely know what they are to be evaluating. If the medical staff were to adopt CPGs, they could be used to guide the proctoring process in terms of what is to be evaluated.

2. Where physicians seek to work with NPPs, who does what, when, is often posed as a confounding concern in establishing the boundaries between NPP functions and physician functions. As long as the NPPs are credentialed, if a group of physicians chose to treat in accordance with a CPG, why couldn't the medical staff privilege the group on that basis? If the medical staff were to adopt a CPG for a condition to be used to determine what should be done for a patient, who is doing what would become less of a concern.

3. Standing orders can be a contentious problem when imposed by the hospital; yet, if in a collaborative process, the medical staff selected good CPGs to drive standing orders and processes of care, imagine how much time could be saved in documentation, including of the scope of the physician's own services in the institution, which he could then use for his own billing while he was meeting the hospital's needs and enhancing quality.

4. The difficulties in effective corrective action often turn on the problems in medical staff members sanctioning their friends and peers. The persuasion and, indeed, even coercion that Executive Committee and Fair Hearing Committee

members are subject to in the corrective action process can be so unpleasant as to impede appropriate action. Above, all the amount of time physicians must spend working up the case and taking it through the fair hearing process is extremely disruptive to those who are dragooned into such service. A medical staff using CPGs could track conformity, evaluate results and if a real problem arises, farm out the investigation and fair hearing processes to be made in accordance with the staff-selected CPGs, with a recommendation back that the staff mechanism would then act upon. This would maintain the integrity of medical staff control, provide clear parameters for the outside reviewers and save the medical staff members for their highest and best use in the process. Without clear parameters for judgment in the form of CPGs, though, this is much more difficult.

Astonishingly enough, the Stark regulations even provide a basis upon which the hospital can actively assist in training medical staff members in ways that will benefit the hospital and the physicians in their own practices. (See 42 CFR §411.357 (o)) The regulation explicitly permits hospitals to supply physicians with training in compliance. The application of CPGs, in broad ways, including those addressed here, as part of that training can impel medical staff quality endeavors while it enhances compliance for the physicians and the hospital.

Conclusion

The organized medical staff performs vital functions for the hospital and must be engaged if

the hospital is to move forward on quality. By coordinating the quality initiatives of the hospital with the physicians' related private practice needs, there can be real power in such an explicit synergy. To expand the medicals staff's role beyond credentialing and privileging can give the hospital far better access to useful expertise and can give the physicians a significantly more meaningful role in shaping their hospital work environment. By rethinking the real value of the medical staff, the physicians can contribute more and get more from the relationship which can only ultimately redound to the benefit of the patients.

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RESOURCES:

- “Making Quality Happen: Confronting the External Challenges to Time and Healing Relationships” (<http://www.gosfield.com/leadaug.pdf>)
- “Making Quality Happen: In Search of Legal Weightlessness”, (<http://www.gosfield.com/ch13pdf.pdf>)
- “Quality and Clinical Culture: The Critical Role of Physicians in Accountable Health Care Organizations” (<http://www.ama-assn.org/ama/pub/category/8340.html>)
- “Whither Medical Staffs?: Rethinking the Role of the Staff in the New Quality Era” (forthcoming, Health Law Handbook, June, 2003)

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