Peer Review Report

News, analysis and commentary on Medical Staff credentialing, privileging, peer review and governance

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NEW JCAHO RULES: MEASURE ALL PRACTITIONERS

Major new JCAHO standards are about to change significantly how hospitals and medical staffs evaluate physicians.

Late last year, the Joint Commission proposed eight new credentialing and privileging accreditation standards (there are presently 13). The new standards, if adopted, will require joint hospital-medical staff efforts to create several new surveillance processes and revise, if not completely restructure, important medical staff documents, including credentialing manuals and privilege delineations.

Prior standards were for the most part an ambiguous, aspirational collection of "shoulds" and "ought tos." JCAHO's new, let-me-spell-it-out-for-you approach ends much of that uncertainty.

Fully 36 new Elements of Performance (EPs)—requirements by which JCAHO grades each hospital at survey—detail as never before how hospitals must create, evaluate and apply privileges and how they must make application decisions.

Perhaps most important, a specific new standard requires a "Continuous Professional Practice Evaluation" of the clinical practice and professional behavior of every privileged practitioner at the hospital. Hospitals must use the results of this evaluation as a "decisive factor" when granting or renewing privileges.

(See New JCAHO Rules, page 6)

What Are The Legal Ramifications of the New JCAHO Rules?

- See **Legal Analysis: Lawyers Must Be Key Players on Revision Teams** on page 4
- The **Commentary** on page 8 sees JCAHO and other legal developments as big steps forward.

In this Issue:

CREDENTIALING CASE: HOSPITAL LETTERS CAN'T MISLEAD

A common credentialing practice may soon get you into big trouble if a recent Louisiana decision becomes law in other states. Many think it eventually will. Many think it's about time.

The case, *Kadlec Medical Center v. Lakeview Anesthesia Associates,* holds that one hospital can't mislead another hospital when sending credentialing information. Those who do mislead may be liable for patient injuries at the receiving hospital.

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. . . Hospital Letters Can't Mislead (cont'd)

Some hospitals answer requests for credentialing information fully and truthfully. Most won't. You know who you are.

Let's set this up briefly. Suppose a physician in your organization has a serious performance problem, and you know it. Maybe you've taken formal action, maybe you haven't. In any case, you have not reported anything to anyone. (You may be right or wrong; if you don't know the difference, you and I need to chat . . . .)

One day, you get a letter from St. Elsewhere Hospital. It's a credentialing office form requesting detailed information about your problem physician. It says she's applying for privileges at St. Elsewhere and asks you specific questions about her competence, behavior, and ability – the usual.

How do you respond to this letter?

One very common response is to return a form letter, stapled to the original request but ignoring the specific questions. The response recites only the dates of membership and that the member is (or was) "in good standing." Your physician, it turns out, stopped admitting patients at your place six months ago, and her membership and privileges expired last month without renewal.

Some hospitals answer the questions fully and truthfully. But despite federal law and state laws like Ohio's (and to a less clear extent, Kentucky's) that protect honest responses, most won't. You know who you are.

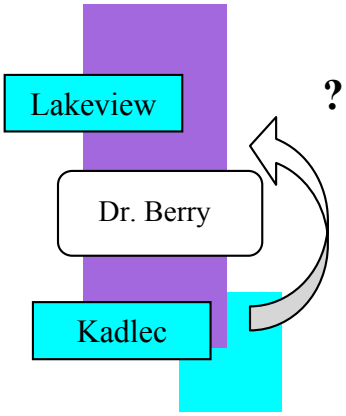
To ice the cake, let's now suppose that a patient at St. Elsewhere later dies. The reason: malpractice by your departed physician. The patient sues: (a) the physician, for malpractice; (b) St. Elsewhere, for negligent credentialing; and (c) you, for not coming clean.

If you're in Louisiana, you'll have to stand trial to prove you didn't mislead St. Elsewhere by failing to answer their questions.

One case is hardly a trend. But it represents further general evidence that legislators, regulators and, now, courts are no longer willing to put up with practices that fail to reduce patient injuries. That 1999 Institute of Medicine report alleging as many as 98,000 deaths a year from medical mistakes is alive and well.

In the *Kadlec* case, anesthesiologist Dr. Lee Berry had a serious Demerol problem. His prior hospital, Lakeview Regional in Louisiana, apparently had suspicions. It looks like nurses knew or suspected drug use. He had failed to properly document his drug utilization. One night, he was unable to work a scheduled case, and the hospital's anesthesia chief found him slumped in a chair.

Berry's anesthesia group promptly fired him. Berry left town, and the hospital did nothing, other than possibly breathe a sigh of relief. His privileges expired a half-year later at the normal end of his two-year appointment.



Lakeview knew about Dr. Berry's drug problem. Nobody told Kadlec, even when they asked about problems.

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Hospital Letters Can't Mislead (conclusion)

Soon after, Dr. Berry applied for anesthesia privileges at Kadlec Medical Center in southern Washington State. As a part of the credentialing process, Kadlec wrote to Lakeview asking specific questions. They got back the short "in good standing" letter.

Kadlec also got letters from two of his former group members (including the chief who fired him) attesting in glowing terms to Berry's excellence, recommending him highly. (It won't surprise you to learn that the group and its members are also defendants and will have some explaining to do at the trial. But that's another story.)

Finding Dr. Berry's record clean, Kadlec granted privileges. About a year later, Dr. Berry left a young mother of three in a coma.

Pharmacy usually did drug profiles to catch unusual drug patterns. They didn't get to it until two days after Dr. Berry hurt someone.

Kadlec's pharmacy periodically tracked drug utilization. Normal anesthesiology Demerol use for the month before the incident was 9 units per physician. Dr. Berry's was over 100. This report was usually done at the beginning of each month. This time, unfortunately, it was not completed until two days after the incident.

Plaintiffs settled the inevitable suit against Dr. Berry and Kadlec in 2003 for $8.5 million. Kadlec paid $7.5 million. Kadlec then went to Louisiana and sued Lakeview for not coming clean on Dr. Berry's drug use.

In a decision last May, the Louisiana trial judge refused Lakeview's motion to dismiss the case. He said that if Kadlec can prove to a jury that Lakeview misled Kadlec during the credentialing process, Kadlec might win.

What was particularly significant about the judge's reasoning was the role that he said JCAHO-mandated credentialing verifications played. Hospitals around the country, he said, occupy "special relationships" among each other in order to protect the nation's patients. That relationship required more than just a back-of-the-hand brush-off. If you say *anything* in a response letter, you have to be complete. Half an answer can cost you money.

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That statement, however, implies that to avoid liability, hospitals (in Louisiana anyway) must either specifically decline to provide any information or ignore the request entirely. Neither of these alternatives would please patients or JCAHO – and good luck when you ask for information – but the question before the court was legal liability for harm, not regulatory compliance.

Much has yet to develop in this case before it becomes the final word. The trial must yet occur. If there is a money verdict, there will surely be appeals. And it is not certain that other states, including Ohio and Kentucky, will follow its reasoning and apply the rule in its own cases.

But until hospitals freely share what they know, those less-than-candid reference letters may cause harm: To your patients, when you get such a letter, if you don't follow up. Or to your hospital, if you write one.

Legal Analysis

Lawyers Must Be Key Players on Revision Teams

The JCAHO sea change in privileging and credentialing probable for 2007 will undoubtedly send hospitals scrambling in 2006. Task forces. Project teams. Budget revisions. Strategy sessions. Implementation schedules.

In the all the hustle, don't forget to include your lawyer.

JCAHO's new credentialing focus on actual in-hospital performance will have profound legal implications. Adding new people and processes will not be enough. You will have to maintain some fairly tricky balances with the law. Do it wrong, and you could be in trouble, either in the form of lawsuits, lost confidentiality or lost immunity. And I'm not even talking about threats to JCAHO accreditation itself.

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We'll discuss Ohio law here (Kentucky law is trickier because of its thin statutory protections), but the questions will be the same in all states.

The tangible end products that will require your attention include the usual suspects. Privileges will need revision to comply with new criteria and performance monitoring requirements. Credentialing manuals and related documents will need updating. Many bylaws will have to be changed. (If you haven't addressed the requirements of MS 1.20, EP 19 on supplementary documents, now's a good time to do that too.) Peer review processes may have to be refined, incident reporting will need new handling and other new mechanisms for surveillance installed.

Many Medical Staff documents will have to be examined and possibly revised.

While non-lawyers may ordinarily perform some of these tasks, there are unique risks this time around because of the close connections to negligent credentialing and physician discipline. Here is a sampling of matters that you will want to take into account:

1. **Loss of Negligent Credentialing Immunity**: You may know that an Ohio statute specifically confers legal immunity from negligent credentialing. You may not know that it can be easily lost. A plaintiff can get around that immunity if he can prove you didn't follow JCAHO's credentialing standards. So if you fail to set up the required new Continuous Professional Practice Evaluation system, for example, you may be liable if your staff doctor hurts someone. As a result, each of these new changes will bear close legal examination to help you decide which ones create the highest risks of immunity loss.
2. **Failure to Follow Your Own Procedures**: It is easy to fall into the opposite trap and create so much new paper and so many new processes that you can't follow them. That can be equally if not more dangerous. A negligent credentialing plaintiff can have a field day pointing to all of the rules that you created but didn't follow. Your lawyer can help you with a risk assessment that guides your response with tempered, simple well-written documents. You are likely to have to do a fair amount to keep both JCAHO happy and your patients safe, but there are simple ways and risky ways of getting there.

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Lawyers Must Be Key Players . . . (conclusion)

Lawyers can help answer confidentiality and immunity questions as well as help you design and structure surveillance processes that will protect you.

3. **Failure to Properly Address Performance Monitoring**: One of the new requirements is that hospitals must examine all their privileges and decide which, if any, will require special performance monitoring. The decision whether to monitor a certain procedure carries obvious legal and risk management implications. The decision to monitor – and then failure to follow through – also creates the "you-didn't-follow-your-own-rule" problem from above. If you do find a problem and act upon it, the action will likely have peer review implications. Lawyers can help you maintain the proper balance among these essentially legal/risk management considerations.

4. **Preserving Peer Review Immunity and Confidentiality**: Most of the new credentialing processes at least touch, if not directly and significantly implicate, Ohio's peer review immunity and confidentiality laws. How much of this new performance monitoring can be protected from court disclosure? Is the entire Performance Improvement department at your hospital now on the hook in a physician suit, or do they enjoy immunity as part of the peer review process? Lawyers can not only help you with the short answers to these questions but also help you design and structure processes that will likely protect you best.

5. **Medical Staff/Hospital Friction**: The new standards require "the organization" to do this, that and the other thing. Formerly, the Medical Staff started the process and produced a recommendation for the board . . . or not. This JCAHO shift to shared responsibility for patient care initiatives has built into it the seeds of conflict. Medical Staffs that work well with their administrations will see no problems. But this new role reassignment has the potential to require mediation between Medical Staff leaders and administrators here and there, for which good counsel are well positioned.

6. **Complaint Process and Incident Reports**: Incident reports in hospitals are specifically but narrowly protected under Ohio statute. The new standards require a process by which pretty much anybody – clinicians, employees and patients – may express "clinical practice concerns" about others. You will want your lawyer to be sure that whatever you put in place takes maximum advantage of the incident report confidentiality law. There are also risk management implications if you fail to properly investigate and respond to reported concerns, so hospitals cannot take this process lightly.

7. **Disruptive Behavior**: While we're at it, this is a good time to fold into your documents and processes the requirements of proposed new Patient Safety Goal 16. This will require, if adopted (and you ought to do it anyway), significant documents, processes and other requirements aimed at managing disruptive behavior. Some medical staffs have done a little, but most have not done much. This goal, moreover, covers not just physicians but all hospital caregivers. Most Medical Staffs will need help either creating workable processes from scratch or coordinating what they have with now required hospital-wide initiatives. How this meshes with peer review, corrective actions fair hearing processes will be the work of your lawyer. (A more detailed discussion of this issue will appear in the next issue of PEER REVIEW REPORT.)

It's easy to put off getting your lawyer involved until the last minute. Avoid that temptation. Early involvement in these inherently legal processes will save you time and money later.

Pssst. Got 15 minutes?

Do you have an upcoming:

- Medical Staff meeting?
- MEC meeting?
- Board meeting?

I'd be happy to give you 15 minutes on any of the topics you see in this newsletter.

Call me for arrangements at 733-1759 or email me at rascolpa@cinci.rr.com.

New JCAHO Rules . . . (continued from page 1)

The new standards, likely to go into effect in 2007, follow a JCAHO task force report that was highly critical of present hospital credentialing efforts. In proposing the new standards JCAHO said:

> "The Task Force concluded that existing processes for credentialing and privileging are ineffective in facilitating continuous performance review, in identifying substandard performance, and in providing for intervention when substandard performance is identified."

"[E]xisting processes for credentialing and privileging are ineffective . . . ."

JCAHO Task Force Report

The three most significant changes, in privileges, credentialing and performance monitoring, will mean a major restructuring of the way leaders must assess the current competence of their privileged practitioners. I will go into more detail on each of these major changes in upcoming PEER REVIEW REPORT issues. A quick summary ought to capture your interest:

- **Privileges**: Each hospital must fully-describe every service it provides in a cooperatively developed privilege delineation document or list. Each privilege must be setting-specific and continuously examined to be certain the hospital has the resources to support it. Each privilege must also state specific criteria against which each practitioner will be consistently and uniformly measured. JCAHO gives you a minimum list, which staffs may supplement. (The days of "wish list" privilege applications are over.) Each organization must also examine its privileges and decide, based on risk, which procedures require special performance monitoring, for both those who are already at the hospital and those who apply new. Hospitals must now go into considerable detail about who gets monitored, when, how, by what means and for how long. As a result of these changes, many if not most hospitals will have to update, revise (or create) their privilege documents.
- **Credentialing Process**: The Medical Staff must now ask for information about competencies comparable to those measured in residency, including "interpersonal and communications skills" and "professionalism." The organization also must decide whether, in each case, it even has enough clinical performance information to grant or renew a privilege in the first place, perhaps a death knell to inactive hospital users. Hospitals must uniformly assess data collected from individual performance evaluations (next bullet) and from the details of the privilege delineation requirements (previous bullet) before making each specific privilege decision.

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New JCAHO Rules . . . (Conclusion)

Every hospital must now collect data pertinent to every practitioner's clinical practice and professional behavior.

- **Performance Monitoring**: The most radical (and likely most expensive) change is JCAHO's addition of a "Continuous Professional Practice Evaluation" requirement. In addition to special monitoring of certain specific procedures, every hospital must now collect data pertinent to every practitioner's clinical practice and professional behavior. JCAHO sets forth a long list of possible things to measure, including clinical outcomes, consultant and pharmaceutical use and length of stay. Ways to measure this performance may include chart review, direct observation and discussions with nurses and administrators. The resulting data must be a "decisive factor" when making privileging decisions.

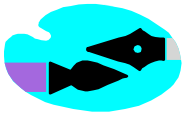
One significant shift concerns who gets to lead the charge on these changes. Previously, credentialing, privileging and performance monitoring was deemed a Medical Staff affair, with administration occupying an approval and executive role. By contrast, these proposed changes put major responsibility for implementing changes on the "organization." One reason for this shift could be that the enormous resource cost of implementation will fall to the hospital. Another possible reason is to provide authority to administrators who are sometimes frustrated by uncooperative medical staffs. Shared responsibility at least gives hospitals some leverage where changes may leave staff physicians less than enthusiastic about taking the initiative.

Taken as a whole, these proposed changes bring a very new focus to credentialing. What used to be processing of a lot of outside paper has turned into an inward look requiring each hospital to pay much closer attention to what physicians are actually doing within its walls. JCAHO has taken a serious step toward trying to link actual current or recent performance to patient safety, rather than rely on residency-based or other second-hand reviews.

The new steps, however well-intended and well-grounded they may be, will be expensive. The amount of data to support the credentialing process, compared to what JCAHO previously required, will be immense. Practice profiles on each practitioner will mean significant increases in people and work time, if the results really are to be a "decisive factor" in the decision.

And the increased resources do not stop internally. Survey preparation consultants will once again play a pivotal role in interpreting what JCAHO will expect to see. Moreover, there are many legal implications to this new world that hospitals and staffs must consider at each step of the redesign process, as the accompanying article in this issue demonstrates. Reconciliation of the legal and the clinical will take some doing.

All these changes are likely to be painful. For the first time in a while, however, they actually seem reasonably aimed at patient care outcomes and safety, rather than just pushing paper around.



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Commentary

Dawn of a New Day?

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Fasten your seat belts. 2006 is likely to be one wild ride.

Within just the last year, several trends in credentialing and peer review have moved us into a brand new world. It was as if simultaneously, but coincidentally, people started to "get it."

Not all of these developments are without problems or concerns. We have a long way to go before many of these ideas grow to their full potential. But on the whole, things are looking up. In no real particular order –

- The Joint Commission looks like it's moving from paper chasing to results measurement. It used to be that survey success depended heavily on what your documents say. Now they care more about what your patients say. With their new credentialing standards (see the lead article in this issue), they want you to measure success and thereby save patient lives. What a concept.

- An obscure Federal Court in Louisiana may be the mouse that roared in the legal arena. As the article in this issue indicates, this court held that in credentialing, one hospital can't mislead another. If this case catches on around the country, more and better information should be available, with smarter decisions to follow.

Rich Setterberg

- A new Patient Safety Goal would bring into focus a serious problem that has confounded health care for some time: Disruptive care givers. Many entities have ignored it altogether. Those that don't often have no idea how to manage it. Finally, and most recently, JCAHO recognizes it's not just doctors; it could be anybody – a CRNA, a floor nurse or a psychologist. JCAHO declared, "Disruption . . . has a negative effect on patient safety." More on this in the next issue.

- At the federal level, even Congress decided that business as usual just won't do. Last summer, President Bush signed the Patient Safety Quality Improvement Act. This act tries its hand at an anonymous reporting and improvement system like the one so successfully used for airplane pilots. The statute isn't perfect, it's unclear how folks will use it, and no one is sure how effective it will be in improving care. But conceptually we have taken a small step away from lawsuits as the go-to mechanism for improvement.

There are still big challenges. Money is the biggest. It's one thing for JCAHO to enact an unfunded mandate. It's another for hospitals to come up with the money. Fear of lawsuits will still keep hospitals wary of freely sharing information until courts prove they will not punish honesty. "Disruption" is still abused as a hammer to silence healthy criticism, get at one's enemies and entrench economic advantage. That has to stop.

Even with faults, however, these are remarkable initiatives. With some heavy lifting, they may prove to be the benchmarks of a new era. Welcome to 2006.

Richard A. Setterberg Co., L.P.A. publishes and distributes **PEER REVIEW REPORT** free to inform clients and others about issues and developments concerning medical staff matters. It is not legal advice. For further information on issues or topics in this newsletter as they may apply to particular facts, please contact the editor at (513) 733-1759 or rascolpa@cinci.rr.com.

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