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Weighing the Options of Appointing Non-Physician Practitioners to the Medical Staff

Jennifer A. Hansen
Katherine M. Dru
Hooper Lundy & Bookman PC
San Diego, CA, and Los Angeles, CA

The Centers for Medicare & Medicaid Services (CMS) issued Final Rule CMS-3267-F (Final Rule) on May 12, implementing several changes (Revisions) to the Medicare Conditions of Participation (CoPs). Among these changes was a revision to 42 C.F.R. § 482.22(a) (Revised CoP) to clarify that while a hospital's medical staff must be composed of doctors of medicine or osteopathy (MDs or DOs), the medical staff also may include other categories of *physicians and non-physician practitioners* eligible for appointment to the medical staff under state law, including scope-of-practice laws. The Revised CoP provides: "The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at

Practice Groups Staff

Trinita Robinson
Vice President of Practice Groups
(202) 833-6943
trobinson@healthlawyers.org

Magdalena Wencel
Senior Manager of Practice Groups
(202) 833-0769
mwencel@healthlawyers.org

K.J. Forest
Senior Manager, Practice Groups Distance Learning
(202) 833-0782
kforest@healthlawyers.org

Brian Davis
Senior Manager, Practice Groups
Communications and Publications
(202) 833-6951
bdavis@healthlawyers.org

Arnaud Gelb
Practice Groups Distance Learning Administrator
(202) 833-0761
agelb@healthlawyers.org

Crystal Taylor
Practice Groups Activities Coordinator
(202) 833-0763
ctaylor@healthlawyers.org

Mark A. Williams
Practice Groups Web and Marketing Coordinator
(202) 833-0756
mwilliams@healthlawyers.org

Dominique Sawyer
Practice Groups Distance Learning Certification Coordinator
(202) 833-0765
dsawyer@healthlawyers.org

Matthew Ausloos
Practice Groups Communications and Publications
Coordinator
(202) 833-6952
mausloos@healthlawyers.org

Jasmine Santana
Practice Groups Editorial Assistant
(202) 833-6955
jsantana@healthlawyers.org

Graphic Design Staff

Mary Boutsikaris
Creative Director
(202) 833-0764
mboutsik@healthlawyers.org

Ana Tobin
Graphic Designer/Coordinator
(202) 833-0781
atobin@healthlawyers.org

§482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body."[1]

In light of this clarification, hospitals must weigh the benefits and risks of appointing non-physician practitioners to the medical staff, including balancing the benefit of increased flexibility with the potential burdens of peer review and credentialing for a wider range of practitioners.

Prior Rule and Need for Clarification

Prior to the Revision, 42 C.F.R. § 482.22(a) provided, "The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body."[2] The language of this CoP left unclear whether the term "other practitioners" was intended to permit the appointment of physicians who are neither MDs or DOs (Other Physicians) to the medical staff, whether the term instead was intended to permit the appointment of non-physician practitioners (Other Practitioners) to the medical staff, or whether the term was intended to permit the appointment of both Other Physicians *and* Other Practitioners to the medical staff.

As CMS explained in its May 20 memorandum on the Final Rule, the Revision to 42 C.F.R. § 482.22(a) was made "to indicate that the medical staff must include MDs or DOs, but may also include other categories of physicians listed at § 482.12(c)(1), as well non-physician practitioners. A prior rule change inadvertently omitted the reference to other categories of physicians."[3]

Categories of Practitioners: Other Physicians and Other Practitioners

The Revised CoP makes clear that a hospital's medical staff may, in accordance with state law, include three categories of practitioners: MDs and DOs, Other Physicians (as listed at 42 C.F.R. § 482.12(c)(1)), *and* Other Practitioners.[4] The Other Physicians enumerated in Section 482.12 include:

- Doctors of dental surgery or dental medicine;
- Doctors of podiatric medicine;
- Doctors of optometry;
- Chiropractors; and
- Clinical psychologists.[5]

These categories are the same as those included in the definition of "physician" contained in Section 1861(r) of the Social Security Act (Act).[6]

The Other Practitioners who may be appointed to the medical staff under the Revised CoP are not set forth in the CoPs. However, in an appendix to its State Operations Manual, CMS explained that Section 1842(b)(18)(C) of the Act defines these Other Practitioners to include:

- Physician assistants (PAs);

- Nurse practitioners;
- Clinical nurse specialists;
- Certified registered nurse anesthetists;
- Certified nurse-midwives;
- Clinical social workers;
- Clinical psychologists;[7] and
- Registered dieticians (RDs) or nutrition professionals.[8]

Importantly, however, the Revised CoP limits the Other Physicians and Other Practitioners who may be part of the medical staff to those whose appointment would be "[i]n accordance with State law, including scope-of-practice laws," and further limits Other Practitioners to those "determined to be eligible for appointment by the governing body."[9] Thus, it is necessary to consult state law to determine which Other Practitioners a hospital may appoint to its medical staff.

For example, in California, MDs and DOs, dentists, and podiatrists are eligible for medical staff membership as a matter of law, and clinical psychologists *may* be eligible for medical staff membership at the option of the hospital.[10] California law makes no affirmative provision for the appointment of doctors of optometry, chiropractors, or any Other Practitioners to the medical staff while, interestingly, among others, marriage and family therapists, professional clinical counselors, and PAs are treated like medical staff members for purposes of reporting and hearing rights under Cal. Bus. & Prof. Code §§ 805 and 809. Thus, even though the Revised CoP expands the range of practitioners who may be eligible for medical staff membership to include certain non-physician practitioners, state law still controls.

Balancing the Benefits/Risks of Appointing Non-Physician Practitioners to Medical Staff

The main benefits of appointing Other Practitioners to the medical staff appear to be time savings, flexibility, and efficiency while the burdens include increased potential costs of oversight and peer review.

In a number of situations, Other Practitioners are the professionals best qualified to assess and develop plans of care for the patient in a timely manner to realize improved patient outcomes at the most efficient cost. For example, many times RDs are the professionals best qualified to assess a patient's nutritional status and to design and implement a nutritional treatment plan in consultation with the patient's interdisciplinary care team. On the other hand, some argue that in certain cases, such as post-abdominal surgery care, the physician is best suited to determine patient diet, and the RD must defer to or consult with the responsible physician for the care of the patient. Therefore, medical staffs must determine which specific practitioners are qualified for which specific privileges consistent with the medical staff bylaws and state law.

The extent of required MD/DO supervision or oversight is another factor that should be considered. For example, if a medical staff includes a dentist as an Other Physician on the medical staff, that dentist still can only provide care and treatment within the scope of practice allowed by state law. For instance, one question that may arise is the extent of that dentist's privileges to admit a patient or perform a history and physical examination. A dentist may be able to admit a patient or perform a history and physical on a patient who only has dental issues where no medical issues of significance exist. If the patient has a clear medical condition (poorly controlled diabetes, a bleeding disorder, etc.), however, the dentist could still potentially admit the patient, but a physician would still need to be involved for both a complete history and physical and to manage the medical condition.

Requirements of the hospital's accrediting body also must be considered in appointing Other Practitioners to the medical staff. For example, The Joint Commission's (TJC's) Standard MS.03.01.03 requires that "[t]he management and coordination of each patient's care, treatment, and services is the responsibility of a practitioner with appropriate privileges," but one of the elements of performance of that standard requires that "a patient's general medical condition is managed and coordinated by a doctor of medicine or osteopathy."[11] Similarly, although TJC's Standards provide that a hospital "may choose to allow individuals who are not licensed independent practitioners to perform part or all of

a patient's medical history and physical examination," TJC requires that such examination be "under the supervision of, or through appropriate delegation by, a specific qualified doctor of medicine or osteopathy who is accountable for the patient's medical history and physical examination."[12] Thus, even if an Other Practitioner may be privileged as part of the medical staff, an MD or DO still must manage and coordinate patient care provided by that Other Practitioner if TJC accredited the hospital.[13]

Before deciding whether to appoint Other Practitioners to the medical staff, it is important to weigh the increased burden on the medical staff to credential and privilege the Other Practitioners where the hospital's human resources department traditionally may have been responsible for oversight of such Other Practitioners. For example, while TJC's Standards already require PAs and Advanced Practice Registered Nurses to be credentialed through the medical staff process or equivalent, this is not a requirement for others falling within the Other Practitioner category. Therefore, the medical staff may face the cost of additional support staff to provide the manpower to handle the paperwork associated with credentialing the Other Practitioners who are not already credentialed through the medical staff process or equivalent. Further, increased administrative burdens may arise as well as the potential for increased attorneys' fees and costs if the medical staff decides to extend peer review to Other Practitioners.

Another broader potential implication of appointing Other Practitioners to the medical staff is the burden of responding to inquiries regarding whether adverse action was ever taken against an Other Practitioner. Appointing Other Practitioners to the medical staff could complicate medical staff's duties and obligations to report and respond to credentialing inquiries.

Middle Ground Alternative: Allied Health Professional Practitioners with Privileges

Importantly, the Revised CoP does not mandate creating new classes of medical staff membership nor does the Revision require that, if some status within the medical staff structure is provided, it be as a medical staff member. As an alternative to providing for full membership to Other Physicians and Other Practitioners, medical staffs that wish to credential and extend privileges to perform certain services to Other Physicians and/or Other Practitioners without encountering some of the risks discussed above may still do so by credentialing them as Allied Health Professionals (AHPs), consistent with state law and the requirements of the hospital's accrediting body. This is, of course, what most medical staffs currently do with such practitioners. The CoP does not mandate any change in this approach.

Accordingly, the traditional "middle ground" between granting full medical staff membership versus having all categories of Other Physicians and Other Practitioners governed through the hospital human resources department remains utilization of the AHP categories when provision for these practitioners is deemed appropriate within the medical staff structure. Practically speaking, a large number of medical staffs currently grant AHPs privileges to perform certain specific services, and this is certainly still an option that is not foreclosed under the Revised CoPs.

Conclusion

As set forth above, new risks come with the potential for increased efficiency associated with appointing Other Practitioners to the medical staff. Therefore, it is important for medical staffs to have clearly defined policies for credentialing and disciplining their members, whether they be MDs/DOs, Other Physicians, or Other Practitioners.

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1 42 C.F.R. § 482.22(a), effective July 11, 2014.

2 42 C.F.R. § 482.22(a), Rev. 78, effective Dec. 12, 2011.

3 *Final Rule—Promoting Efficiency, Transparency, and Burden Reduction; Part II—Informational Only*, CMS, Center for Clinical Standards and Quality/Survey & Certification Group, Memorandum of May 20, 2014 from Director of Survey and Certification Group to State Survey Agency Directors, at p. 4, *available at:* www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-33.pdf.

4 42 C.F.R. § 482.22(a).

5 42 C.F.R. § 482.12(c)(1).

6 *See* 42 U.S.C. § 1395x.

7 Note that, under the Social Security Act, clinical psychologists may be either "physicians" or "other practitioners," depending on classification by the medical staff and the hospital's governing body, and in accordance with state law.

8 42 U.S.C. § 1395u. *Cited in State Operations Manual, Appendix A—Survey Protocol, Regulations, and Interpretive Guidelines for Hospitals,* CMS, Rev. 116, 06-06-14, at p. 174, *available at*: www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.

9 42 C.F.R. § 482.22(a), effective July 11, 2014.

10 Cal. Code Regs., tit. 22, § 70703(a).

11 The Joint Commission, *Comprehensive Accreditation Manual for Hospitals,* Update 2, September 2012, at p. MS-17, *Standard MS.03.01.03* and *Elements of Performance for MS.03.01.03*, no. 3.

12 *Id.* at p. MS-16, *Elements of Performance for MS.03.01.01,* no. 9. The Joint Commission defines "licensed independent practitioners" to include physicians, oral and maxillofacial surgeons, dentists, podiatrists, and some advanced practice registered nurses. *Id.* at p. MS-15, *Rationale for MS.03.01.01*.

13 In light of the Final Rule's various Revisions, TJC issued revisions to its Comprehensive Accreditation Manual for Hospitals on August 21, 2014. However, none of these revisions address the Revised CoP or the appointment of Other Physicians and Other Practitioners to the medical staff. *See* The Joint Commission, *Prepublication Requirements*, August 21, 2014, *available at*: www.jointcommission.org/assets/1/6/HAP_Burden_Reduction_Aug2014.pdf.

No-Cause Terminations and Data Bank Reports: Does a No-Cause Termination Mean No Lawsuit?

Susan O. Scheutzow
Sean P. Malone
Kohrman Jackson & Krantz PLL
Cleveland, OH

"No-cause" termination provisions in physician employment agreements are sometimes seen as a way of avoiding the kind of messy hospital-physician disputes that can arise upon termination of an employment relationship. Hospitals use these clauses to part ways with allegedly trouble-making physicians with no questions asked, without a costly peer review process, and without having to make a National Practitioner Data Bank (Data Bank or NPDB) report that can generate lawsuits for defamation, interference with business relationships, or bad-faith peer review. Physicians, too, sometimes prefer such clauses because they promise a clean walkaway from a troubled employment arrangement without embarrassing investigations and reports to the Data Bank or state medical boards.

Often when physicians on a hospital medical staff are employed by the hospital, or an entity owned or affiliated with the hospital, the hospital's human resources (HR) staff investigates the physician's behavior, and the HR department handles the termination process without any peer review process under the hospital's bylaws. Hospital executives and administrators—not the medical staff—meet to discuss the physician's allegedly disruptive conduct. And ultimately, when HR's investigation concludes, the physician is terminated via the contract's no-cause provision.

In such cases, everyone may feel that using the no-cause provision allows for a resolution that is as amicable as possible. The hospital administration believes it can sever the relationship without giving the physician reason to sue for wrongful termination. The medical staff believes that the hospital can extricate itself from a disruptive situation without incurring the time, expense, and emotional turmoil that often ensues when the medical staff has to review one of its colleagues, not to mention the potential liability and lawsuit. Even the physician may be relatively satisfied with the approach, as the physician often can avoid having to pay back signing bonuses, purchasing tail insurance, or adhering to other requirements triggered when a hospital terminates an agreement for cause. Unfortunately, it is not always that simple.

The Reporting Dilemma

For one thing, it goes without saying that a no-cause termination clause cannot protect a hospital from an allegation that it fired a physician for an unlawful reason, such as race, sex, or age discrimination, or to benefit another physician by removing competition.

In addition, absent careful drafting and forthright discussion during the negotiation of physician-hospital employment agreements, a no-cause termination easily can lead to a dispute over a non-compete clause. Hospitals often want non-competes to apply no matter how an employment is terminated, including when no-cause provisions are invoked. Particularly in the case of a troublesome physician, the hospital often will simply want to cut all ties with the physician. Physicians, however, often will want any non-compete clause to apply only if termination occurs due to the physician's breach of contract or if the physician invokes the no-cause termination provision. Understandably, physicians want to avoid being forced to uproot their lives and move out of a service area if the hospital elects to terminate an agreement without cause. The application of a non-compete clause in the event of a no-cause termination is one of the most frequently debated issues during employment negotiations.

Yet an even more challenging dilemma arises when an employment contract provides that a physician's medical staff privileges terminate automatically upon termination of the employment agreement, even when a no-cause termination occurs and there has been no medical staff review. Such provisions are meant to avoid the awkward scenario of a physician, whose employment is terminated, remaining on the medical staff, which will occur unless a hospital is a completely closed system where only employed physicians can practice. The goal is for hospitals and physicians to completely part ways without involving the medical staff in a peer review process and without requiring physicians to resign their medical staff privileges. Some hospitals, particularly in service areas with a single physician, even rely on these provisions in the place of non-competes. If the physician is automatically removed from the medical staff, and the physician receives word that a reapplication would not be looked upon favorably, the hospital can use these clauses to keep the physician from working at the hospital, and depending on the nature of the physician's practice, this may even cause the physician to leave the service area.

But does an automatic termination of the physician's staff privileges pursuant to such a provision oblige the hospital to make a Data Bank report? In the past, hospitals and physicians often have taken for granted that no report is required, but there is growing evidence that the Data Bank disagrees.

The Law

The Health Care Quality Improvement Act (HCQIA), meant to keep physicians from moving from hospital to hospital without disclosing prior malpractice cases or clinical competency problems, requires that "each health care entity which takes a professional review action that adversely affects the

clinical privileges of a physician for a period longer than 30 days" make a report with the Data Bank.[1]

HCQIA defines "professional review action" as:

> an action or recommendation of a professional review body[2] which is taken or made in the conduct of a professional review activity, which is based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the clinical privileges, or membership in a professional society, of the physician.[3]

A "professional review activity" is defined in turn as:

> an activity of a health care entity with respect to an individual physician: (A) to determine whether the physician may have clinical privileges with respect to, or membership in, the entity, (B) to determine the scope or conditions of such privileges or membership, or (C) to change or modify such privileges or membership.[4]

Thus, under the statute, a professional review activity is an investigative activity meant to determine whether to place restrictions on a physician's clinical privileges, i.e., to take a "professional review action," because of medical incompetence or professional misconduct that might affect patient care.

The Health Resources and Services Administration's (HRSA's) own publication, the National Practitioner Data Bank Guidebook, specifically instructs that a Data Bank report should not be filed when a hospital uses its HR department to terminate a physician instead of engaging in medical staff review of the physician's performance before revoking the physician's privileges. According to an example in the Data Bank Guidebook, where a hospital used its "employment termination procedure . . . to end a practitioner's employment," rather than the "system of professional review established under its bylaws," the government "directed that the report be voided from the NPDB since the professional review process had not been followed in terminating the practitioner's privileges."[5] According to the Guidebook, this termination "was not a professional review action. . . . Health care entities are reminded that in order to be reportable to the NPDB, adverse actions must be the result of professional review."[6]

This guidance, coupled with the litigation risk[7] of making an allegedly improper Data Bank entry, means that most hospitals have declined to make a report when staff privileges automatically terminate as a result of relying on a no-cause termination clause. Now, however, the Data Bank's view on this issue may be shifting to the point that hospitals failing to make a report in these circumstances risk incurring fines and losing HCQIA immunity.

In recent years, concerned about underreporting of professional review actions, the government has contacted hospitals directly that are known to have never made a Data Bank report to remind them of their obligations and the civil penalties that can be imposed for failing to meet them. The Data Bank's website describes "Hospital Reporting" as "The Next Compliance Effort."[8] Statistics from HRSA, which manages the Data Bank, show that as of 2011, 47% of hospitals had never reported a revocation or restriction on a physician's privileges.[9]

A recent Dispute Resolution Decision by the U.S. Department of Health and Human Services' (HHS') Division of Practitioner Data Banks also seems to require the reporting of no-cause terminations that result in the loss of privileges. In this decision, the Data Bank appears to take the position that a "professional review action" does not require an actual peer review process, and that an investigation and review performed by the hospital's HR department and administration may constitute an "investigation" for purposes of Data Bank reporting. This view also seems to be manifesting itself in the draft of the proposed updated Data Bank Guidebook, which maintains that "[f]or NPDB reporting purposes, the term 'investigation' is not controlled by how that term may be defined in a health care entity's bylaws or policies and procedures" but offers no further guidance on what HRSA believes an "investigation" is for reporting purposes.[10]

The Data Bank's evolving view will require a major change of behavior for hospitals that employ their physicians. Health care entities across the United States frequently terminate employed physicians using no-cause provisions and employment-related procedures without making Data Bank reports. If the government wants to encourage reporting of no-cause terminations that result in termination of privileges, even without medical staff review, then the revised Data Bank Guidebook should reflect this view. And hospitals should prepare for more physician lawsuits, especially since hospitals effectively remain the sole arbiters of whether a particular action is reportable, i.e., based on the physician's competence or professional conduct and adversely affecting patient health.

Practice Pointers

So what can hospitals do, in the face of this apparent interpretive shift, to avoid a physician lawsuit on the one hand and the Data Bank's censure on the other?

One possibility is to eliminate contract provisions that automatically terminate privileges on the cessation of employment. Instead, when no-cause terminations are used, hospitals can try to ensure that non-compete restrictions remain intact so that once the physician's staff privileges expire, the physician is barred from reapplying. Although the physician may object to the restrictive covenant, at least no Data Bank report would be required upon the expiration of privileges, so long as the hospital has closed any pending investigation by that time.

In the alternative, even if a full-blown, formal peer review process never occurs, hospitals can at least attempt to approximate one by offering a review by the medical staff, and some opportunity for physicians to present their sides of the story. A hospital can forfeit its HCQIA immunity by making a Data Bank report without providing a fair hearing process. If the hospital believes a no-cause termination merits a Data Bank report, it should try to offer some form of medical staff review first. The medical staff may even conclude that no clinical reason exists to terminate the physician's privileges, which would presumably relieve the hospital of any reporting obligation. Practically, many physicians whose hospital employment is terminated will not want to retain clinical privileges at the institution anyway, and they may not even contest the termination of privileges.

Another possibility is for hospitals and physicians to carve out an exception, whenever no-cause terminations are invoked, to clauses requiring the automatic relinquishment of privileges upon termination of employment. Or hospitals can draft their bylaws to specify whether an automatic termination of privileges, concurrent with an employment termination, will or will not be considered a reportable adverse action. If HHS is called to review whether a reportable "professional review action" has occurred, HHS is obliged to consider the hospital's bylaws.[11] Hospitals may even consider including "change-of-law" provisions in their physician employment contracts, allowing the parties to renegotiate certain key provisions in the event that the Data Bank's apparent change of view on these issues becomes settled law. Regardless of HHS' interpretation, clarity and transparency in the hospital's contracts and bylaws puts physicians on notice of these issues, perhaps even allowing the parties to negotiate at the time of hiring on the issue of whether a report will be made upon termination.

Finally, when it comes to making the Data Bank report itself, hospitals should take extra care. Those preparing the online filing confront a drop-down menu of choices that they can use to describe the "Basis for Action" when terminating privileges, including "abusive conduct toward staff" (D4), "disruptive conduct" (D5), and "other unprofessional conduct, specify" (D8). Data Bank filers must include a narrative description of the circumstances involved. HRSA advises filers to "describe the action in enough detail so that future queriers have a clear understanding of what the practitioner is alleged to have done and the nature of and reasons for the event that lead to the report action or surrender" of privileges.[12] HRSA encourages filers to "summarize the committee or board's official findings" and describe the process and circumstances in as much as 4,000 characters.[13]

Crafting this narrative can be tricky for hospitals striving for accuracy about what they believe to have been disruptive behavior but also trying to avoid a lawsuit. Perhaps the Data Bank could offer a new "Basis for Action" option entitled, "Privileges Contractually Terminated Upon Termination of Employment," and make the inclusion of a narrative optional. This may satisfy the government's goal of increasing reporting while allowing hospitals to take a more tactful approach and removing some of the stigma that physicians fear from Data Bank entries.

The government is concerned that, some 20 years after its inception, the Data Bank remains a relevant tool for increasing transparency and improving quality of care, even as large health care systems with employed physicians increasingly dominate the market. But hospitals need clarity as to their reporting obligations and peace of mind that complying with federal reporting policy will not invite more litigation. Physicians need assurances that they can pursue work elsewhere after a hospital employment ends and that a Data Bank entry will not necessarily doom their careers. As the Data Bank's reporting policies continue to evolve, hospitals and physicians should review their employment contracts, try to discuss these issues at the outset of employment, and take extra care in preparing Data Bank entries relating to no-cause terminations.

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1 *See* 42 U.S.C. § 11133(a)(1)(A).

2 "Professional review body" is defined as "a health care entity and the governing body or any committee of a health care entity which conducts professional review activity, and includes any committee of the medical staff of such an entity when assisting the governing body in a professional review activity." *See* 42 U.S.C. § 11151(11).

3 *See* 42 U.S.C. § 11151(9).

4 *Id.* § 11151(11); *see also* 45 C.F.R. § 60.3.

5 NPDB Guidebook, at F9 (Sept. 2001).

6 *Id.*

7 While HCQIA provides no private cause of action for an improper Data Bank report, courts have recognized claims for interference with business relationships, negligent or intentional infliction of emotional distress, and defamation. There also are various state law reporting requirements that can give rise to lawsuits.

8 *See* www.npdb.hrsa.gov/enews/Aug2012enews.jsp#Compliance.

9 *See* www.usatoday.com/story/news/nation/2013/08/20/doctors-licenses-medical-boards/2655513/.

10 *See* www.piaa.us/docs/GR/NPDB_Guidebook_Draft.pdf *available at:* E 31. The Data Bank is on the verge of publishing a revised Guidebook for the first time since 2001, and HRSA made a draft available on November 22, 2013. *See* www.npdb.hrsa.gov/news/news.jsp (Feb. 7, 2014 news entry: "Public Comment Period on Revised NPDB Guidebook Closes").

11 *See* Guidebook at E-21 ("Whether particular actions are reportable to the Data Bank is often best determined by examining a hospital's medical staff by-laws, rules and regulations with regard to provisions defining… what constitutes a professional review action that adversely affects the clinical privileges of a practitioner…."); *Simpkins v. Shalala*, 999 F. Supp. 106, 116 (D.D.C 1998) (reversible error for HHS not to consider a hospital's bylaws when reviewing the validity of a Data Bank entry; concluding that a Data Bank report "should be removed" because "the Secretary's failure to follow [the bylaws listing specific investigatory procedures] or from all appearances even consider these provisions, renders the Secretary's action arbitrary and capricious").

12 *See* www.npdb.hrsa.gov/hcorg/submittingAFactuallySufficientNarrative.jsp.

13 *Id.*

Unified Medical Staffs Are Finally Permitted . . . Now What?

Steve R. Kleinman
Jeremy R. Morris
Kim S. Parks
Bricker & Eckler LLP
Columbus, OH

After considerable time and debate, the Centers for Medicare & Medicaid Services (CMS) finally issued revisions to the Medicare Conditions of Participation (CoPs) that allow the combination of separate hospital medical staffs into a single unified medical staff. CMS previously resisted requests to permit a single unified medical staff within a multi-hospital system. Comments published in the *Federal Register* (FR) noted CMS' historical position "that each hospital, even those in a multi-hospital system, must have its own medical staff with the authority and responsibility for the quality of patient care provided in that hospital."[1] All of that changed when CMS reversed course in a final rule published in the FR on May 12.[2] While the flexibility to combine the medical staffs of system hospitals into a single unified medical staff is a step forward, the devil involved in such a potential combination remains in the details.

What the Rule Requires

To be eligible to utilize a combined medical staff under the final rule, multi-hospital systems must establish that they have met four basic criteria. First, the medical staff members holding privileges at each separately certified hospital must vote, by a majority and consistent with their respective bylaws, to either: (1) accept a unified and integrated medical staff structure; or (2) opt out of such structure and maintain a separate and distinct medical staff for their hospital. Second, the unified medical staff must have appropriate bylaws, rules, and requirements that describe its process for self-governance, appointment, credentialing, and peer review, and must include a process whereby the members of each separately certified hospital are advised of their right to opt out and return to a separate and distinct medical staff. Next, the unified medical staff must be established in such a way that takes into account each member hospital's unique circumstances and significant differences in patient populations and services offered. Finally, a unified medical staff must give due consideration to the needs and concerns of members of the medical staff regardless of location or practice, and mechanisms must be in place to assure localized issues are duly considered and addressed.

The Rule's Ambiguity

Before addressing the logistical concerns associated with attempting to combine separate medical staffs, the new rule's basic requirements contain some interesting language sure to bring about questions. The rule's new requirements make reference to "all medical staff members who hold specific privileges to practice at that hospital"[3] when discussing those medical staff members entitled to vote on whether to accept or reject the unified medical staff and those medical staff members who have the right to potentially vote to opt out of

a unified medical staff structure and return to independent medical staffs. Ordinarily, a medical staff's governing documents define those appointment categories that have the right to vote and those that do not. This issue is complicated by the fact that many medical staffs have individuals appointed to the medical staff with clinical privileges, but in categories that do not necessarily have the right to vote. The language of this rule, when taken literally, appears to call into question whether all medical staff members with clinical privileges have the right to vote on whether to become a unified medical staff or whether to subsequently opt out of a unified medical staff. It would seem somewhat out of the ordinary for a rule such as this to unilaterally alter all medical staffs' governing documents by attempting to define those members who have the right to vote on this issue. Nonetheless, the rule explicitly defines members of the medical staff as "all medical staff members who hold specific privileges to practice at that hospital" on multiple occasions. If a provider is attempting to unify hospital medical staff, due consideration must be given to determining those individuals who have the right to vote on this issue.

Logistical Concerns

As noted above, the ability to unite medical staffs is a welcome change but actually effectuating such combination may include challenges. Those challenges may be worth tackling due to the benefits of a combined medical staff. A combined medical staff could improve existing peer review processes, improve patient safety through shared credentialing and privileging, establish more-efficient sharing of knowledge between members of the medical staff, allow for better on-call coverage for specialties, and help move toward a more-efficient coordination of care as health care delivery systems are modernized.

The revised rule only became effective on July 11. As such, clear solutions to the issues identified below are not yet available, but it is imperative for hospital systems to recognize and address these issues when attempting to unify medical staffs.

First, a hospital system that wants to combine its existing medical staffs must initially determine whether the existing separate medical staffs would be amenable to such a change. As noted above, the ability to combine medical staffs requires the approval of each medical staff. Obtaining the necessary approvals is sure to be a long and difficult process. Before beginning, the hospital system should have a dialogue with each medical staff to gauge interest in the project, determine the concerns of each medical staff, and identify potential solutions to those concerns. The more effectively a hospital system addresses the concerns raised by its medical staffs, the more likely the system will succeed in obtaining the necessary approvals. Hospital systems must work with existing medical staffs to create a combined medical staff. A collaborative approach between the medical staffs and the hospital system's administration is not only recommended, it is necessary.

Once a hospital system obtains the initial set of approvals from its medical staffs, it must remember that the collaborative effort is not over. The new rule also requires that the new governing documents for the combined medical staff:

> include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure . . .[4]

Thus, the rule permits the membership of a particular separately certified hospital to subsequently opt out and return to its status as a separate and independent medical staff. This provision is troubling because a hospital system is always one vote away from disintegration of its combined medical staff. However, guidance issued by CMS on September 15 indicates that the bylaws, rules, and requirements may establish a minimum interval between acceptance and opt-out votes as a method to potentially reduce the risk of an opt-out, which may be considered as a method to reduce disruption.[5] The guidance also indicated that such restrictions should not unduly restrain the rights of the members of a medical staff, and that intervals of more than two years might unduly restrain the medical staff members' rights. Nonetheless, given the possibility that one vote could fracture an integrated medical staff, it is advisable for the hospital system to not only continue to work with the integrated medical staff to address concerns, but also to continue to work with the medical staff members from each separate hospital. While it may be difficult to identify methods to address concerns raised by separate hospitals, putting such a mechanism in place might help ensure that all medical staff members feel as though their voices are heard, which will decrease the potential that a hospital will subsequently attempt to opt out and return to a separate medical staff. Any hospital system considering a combined medical staff must keep in mind that such a move may not be permanent. Accordingly, systems should be aware of the potential of a subsequent opt-out before determining whether the attempted combination is worth the effort.

As noted above, the rule's third requirement mandates that a combined medical staff take into account each hospital's unique circumstances. The final rule does not address how to measure compliance with this particular mandate. A hospital system that combines its medical staffs will have to determine how to best accomplish this objective, and to develop a process whereby each separate hospital has the ability to have its unique qualities acknowledged and addressed.

Similarly, the final rule does not address the manner in which mechanisms to ensure localized issues are duly considered and addressed. Each hospital system will have to evaluate the localized issues with which they are confronted to determine an appropriate method to address those issues.

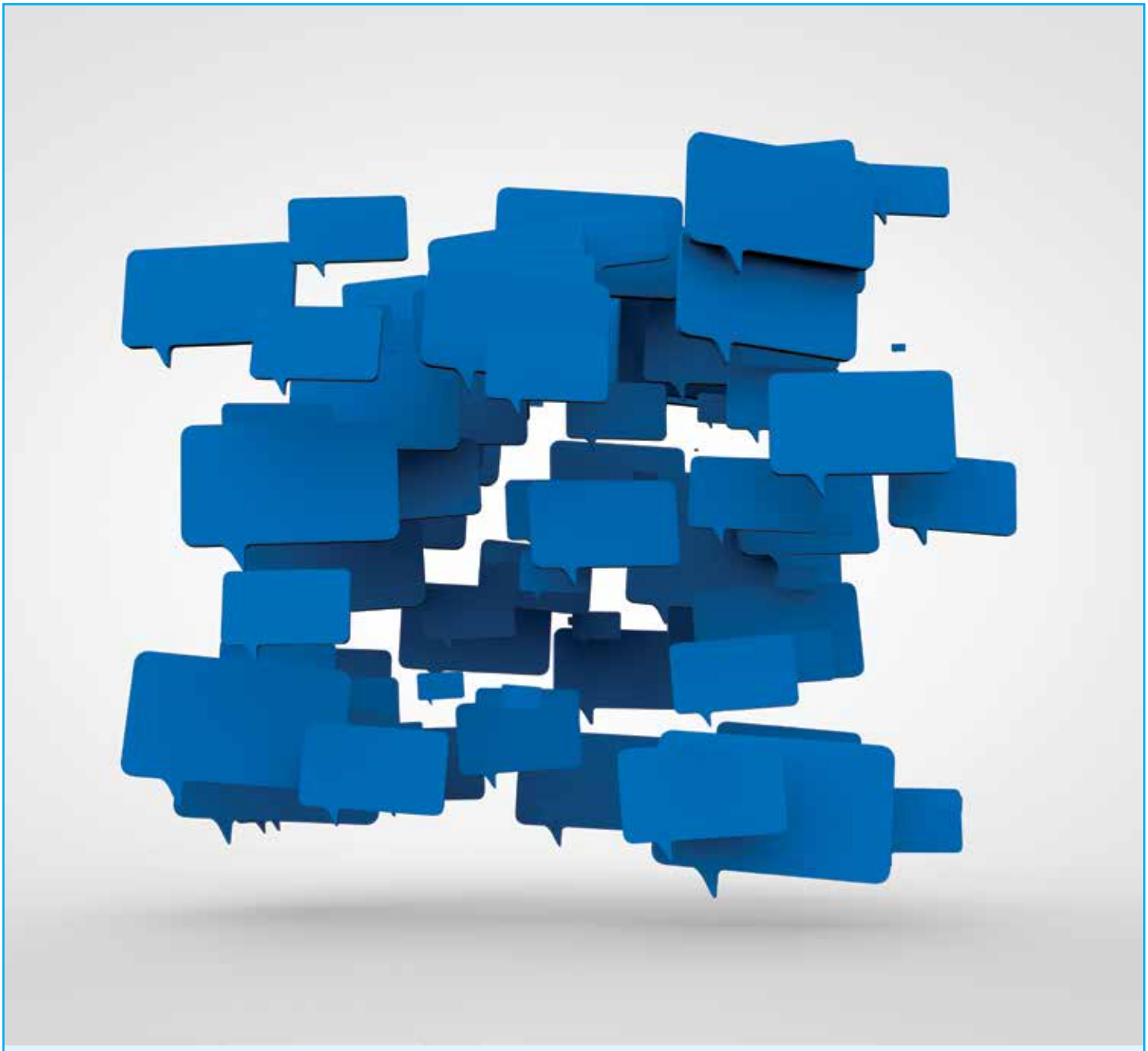
In addition, hospital systems also will have to consider questions the final rule does not answer. One of those questions is

whether a hospital system could form multiple medical staffs. For example, could a five-hospital system form two integrated medical staffs, one that consists of two separate hospitals and one that consists of three separate hospitals, or must such a system combine all five hospitals into one integrated medical staff? Questions of state law also may be at issue. Consider hospital systems that stretch across state lines. Would state laws that govern the practice of medicine in each individual state make a combined medical staff impossible? It could prove to be difficult to draft a uniform set of governing documents for multiple hospitals in different states, depending on the state laws concerning the practice of medicine. Once again, it might be possible for a hospital system to work through this issue, but it must be identified and addressed in this process.

Conclusion

While the ability of hospital systems to unite separate medical staffs into a unified staff is a positive step forward, it will be necessary to carefully consider this final rule and the issues it raises before jumping into an integration project. Many of these questions will be answered by the development of industry best practices brought about by the experience of those who participate in integration projects or by the issuance of additional guidance from CMS. Until then, hospital systems must determine the best methods for addressing these unanswered questions.

1 *See* 77 Fed. Reg. 29062, May 16, 2012.
2 *See* 79 Fed. Reg. 27106, May 12, 2014.
3 79 Fed. Reg. 27108, May 12, 2014.
4 *Id.*
5 *See* www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-45.pdf.



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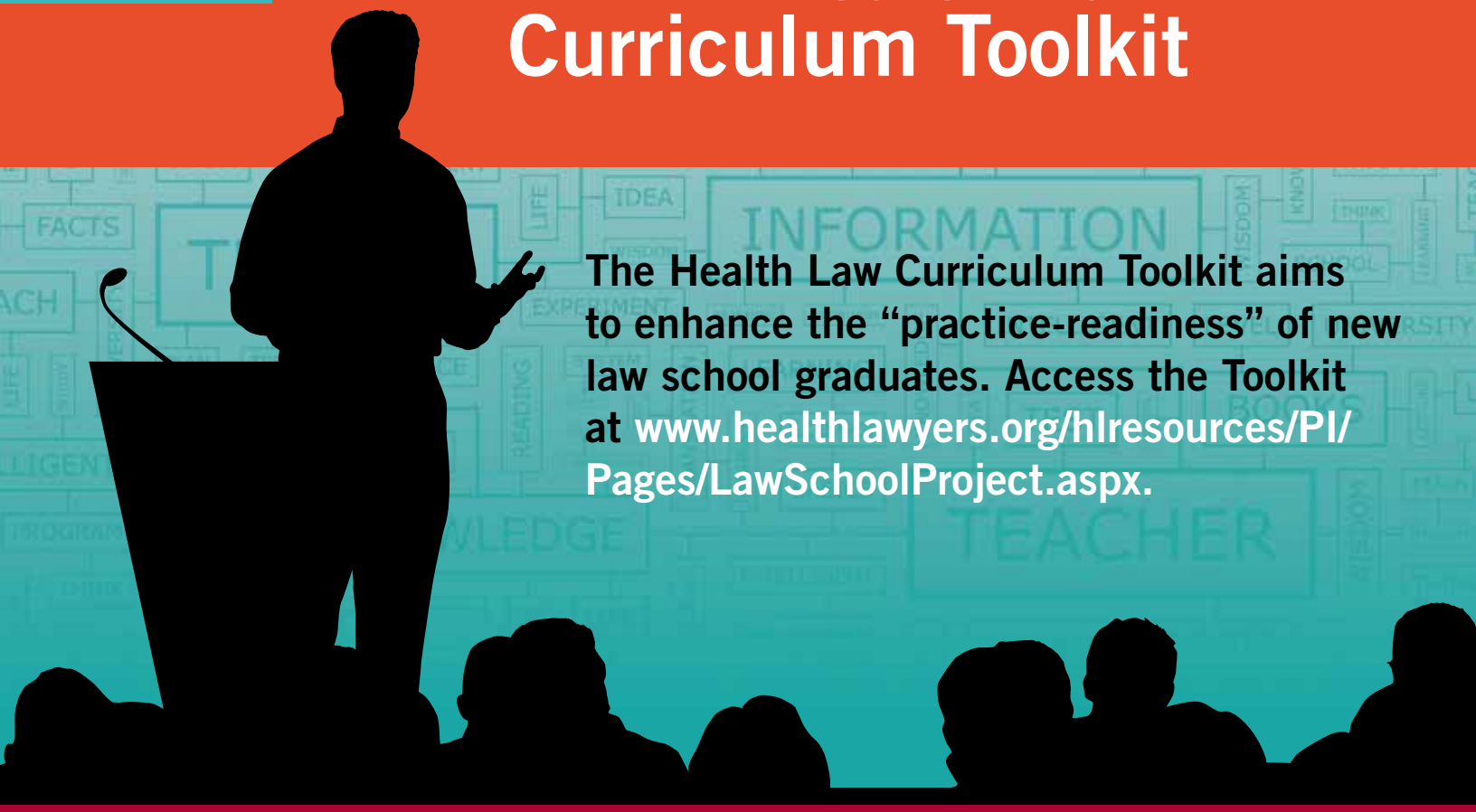

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1620 Eye Street, NW
6th Floor
Washington, DC 20006-4010