What hospital medical staffs and their members need to know about the new Medicare Conditions of Participation

Background

In May 2014 the Centers for Medicare & Medicaid Services (CMS) published a final rule revising the Conditions of Participation (CoPs) for hospitals. Since 2011 the American Medical Association and its Organized Medical Staff Section (OMSS) have been strongly advocating to protect and enhance the role of the medical staff throughout various iterations of these regulations.1

The final rule, which became effective July 11, 2014, makes two major changes to the hospital governance structure:

In the past, each hospital was required to have its own organized medical staff. Under the new regulations, a multi-hospital health system is now permitted to have a unified, system-wide medical staff, provided that each individual medical staff within the system has voted to accept the unified staff structure. Medical staffs incorporated into a unified staff structure retain the right to “opt out” of the unified staff and reestablish a separate, hospital-specific medical staff at a later date. The concept of a unified medical staff had been raised multiple times by other stakeholders and was pushed back by the AMA a number of times before being adopted in 2014.

The final rule also eliminates a previously finalized requirement that the hospital governing body include a member of the medical staff. That requirement, which was included at the suggestion of the AMA, has now been modified to require only that the governing body consult at least two times per year with the individual assigned responsibility for the medical staff (presumably, but not necessarily, the medical staff president or chief of staff).

Most recently, on July 1, 2014, the AMA and more than 80 other medical associations sent a letter to CMS objecting to these changes and requesting a one-year delay of the implementation of the rule, arguing that medical staffs need more time to prepare and that CMS must provide guidance on a number of issues before the rule can be implemented. CMS declined the AMA’s request for delayed implementation, and hospital systems may thus immediately begin to seek a unified medical staff structure.

The following resources, which will be included in a forthcoming edition of the AMA’s Physician’s Guide to Medical Staff Organization Bylaws, are intended to guide medical staffs through the process of deciding whether to join a unified medical staff and to assist them in developing appropriate medical staff bylaws language to implement that decision:

   **Section I:** Discussion guide outlining issues medical staffs should consider when discussing whether to accept a unified medical staff structure and whether to opt out of a previously unified staff structure.

   **Section II:** Sample medical staff bylaws language to assist medical staffs in implementing the new rules.

---

1. AMA communicated its concerns and suggestions to CMS on the proposed regulations five separate times: December 2011, June 2012, April 2013, June 2014, and July 2014. These communications are available in full on the AMA website.
regulations while preserving self-governance and the medical staff’s ability to ensure the delivery of safe, high-quality patient care.

**Appendix:** Relevant hospital Conditions of Participation.

Please contact Keith Voogd, director, AMA-OMSS, at keith.voogd@ama-assn.org or (312) 464-4539 with any questions or comments about these resources. Medical staffs are also encouraged to contact the AMA-OMSS to report and seek assistance on any problems that arise as a result of the new regulations.

Visit the [AMA website](http://www.ama-assn.org) to learn more about the AMA-OMSS and its work on behalf of medical staffs and their members.
Section I: Medical staff unification/disunification discussion guide

Under certain circumstances, medical staff unification may be an attractive option for medical staffs and their members. In other circumstances, however, unification may seriously impede the ability of medical staffs to ensure the quality and safety of care provided to patients across the system.

Before deciding whether to accept a unified, system-wide medical staff, the medical staff must carefully weigh the potential costs and benefits of this decision. The following checklists are presented as a starting point for medical staff discussions regarding unification and disunification. Because circumstances vary widely across hospitals and systems, these checklists may not comprehensively address the circumstances of every medical staff.

<table>
<thead>
<tr>
<th>Issues to consider before your medical staff votes to become part of a unified, system-wide medical staff:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potential costs of unification</strong></td>
</tr>
<tr>
<td>☐ Reduction of medical staff connection with or representation on the governing body</td>
</tr>
<tr>
<td>☐ Disenfranchisement of smaller medical staffs with smaller ratio of members</td>
</tr>
<tr>
<td>☐ Loss of community standards</td>
</tr>
<tr>
<td>☐ Loss of hospital-specific services</td>
</tr>
<tr>
<td>☐ Loss of influence over medical staff bylaws, rules and regulations, and policies</td>
</tr>
<tr>
<td>☐ No recognition of variances in staffing, equipment in support of medical practice between hospitals</td>
</tr>
<tr>
<td>☐ State law peer review protection may not apply</td>
</tr>
<tr>
<td>☐ System-wide obligations, such as ER call</td>
</tr>
<tr>
<td>☐ Imposition of system bylaws that may not be physician-friendly</td>
</tr>
<tr>
<td>☐ Unified medical staff subject to a potentially disruptive disunification vote at any time</td>
</tr>
</tbody>
</table>
**Issues to consider before your medical staff votes to opt out of a previously unified, system-wide medical staff:**

<table>
<thead>
<tr>
<th>Potential costs of disunification</th>
<th>Potential benefits of disunification</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Loss of system contracts, education opportunities</td>
<td>☐ Restoration to status quo before unification</td>
</tr>
<tr>
<td>☐ Loss of state peer review protections applicable to unified staff</td>
<td>☐ Return to state peer review protections</td>
</tr>
<tr>
<td>☐ Access to broader clinical resources</td>
<td>☐ More direct relationship with Governing Body</td>
</tr>
<tr>
<td>☐ Return to local politics</td>
<td>☐ Greater medical staff self-governance</td>
</tr>
<tr>
<td>☐ Bylaws will require amendment to reflect different medical staff structure</td>
<td>☐ Bylaws may be restored to pre-unification bylaws</td>
</tr>
</tbody>
</table>
Section II: Sample medical staff bylaws language

The sample medical staff bylaws language presented below is consistent with the AMA’s understanding of Title 42 §482.12(a)(10) and §482.22(b)(4) and the CMS State Operations Manual, Appendix A, as of September 26, 2014 (see Appendix). Although the AMA will continue to monitor this situation and revise this language as new information becomes available, medical staffs are advised to consult knowledgeable medical staff attorneys before amending their bylaws.

Medical staff unification/disunification processes

Under the new regulations, CMS permits a multi-hospital system to maintain a single, unified medical staff, provided that the members of the medical staff of each individual hospital “have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital” (Title 42 §482.22(b)(4), emphasis added).

The medical staff’s decision to accept a unified staff structure should not automatically invalidate the existing medical staff bylaws, even though this decision could be used as an excuse to replace the existing bylaws with system-level bylaws. Instead, the medical staff must amend or replace (i.e., amend by substitution) the existing bylaws according to the medical staff-driven process set forth in the existing bylaws.

Because acceptance of unification is at least as significant a change for the medical staff organization as amending the medical staff bylaws, the threshold required to make this decision should be at least as high as the threshold required to amend the bylaws (typically, a 2/3 vote). Arguably, given the extraordinary nature of this decision and its potential to divide the medical staff, the threshold should be even higher. For example, the medical staff may wish to consider requiring a 100 percent quorum for a vote to unify, meaning that 2/3 of all members with voting rights, not just 2/3 of those who actually cast votes, must affirmatively accept a unified staff structure—under this quorum requirement, an individual with voting rights who does not cast a vote is counted as a vote against unification.

CMS’s requirement that the vote to unify be made “in accordance with medical staff bylaws” presents ample opportunity for the medical staff to ensure that unification/disunification occurs only after careful deliberation and only when such action is supported by a substantial portion of the medical staff’s membership.

Note that regardless of whether a multi-hospital system decides to pursue a unified staff structure and regardless of whether the medical staff decides to accept a unified staff, every medical staff in a hospital that is part of a system must amend its bylaws to define the processes by which the medical staff votes on unification/disunification. Medical staffs whose hospitals are not yet parts of systems should consider including a process for votes on unification/disunification, so as to be better prepared should the hospital someday be acquired by or otherwise incorporated into a system with a unified medical staff.
Sample bylaw: Medical staff unification/disunification

(1) Unification With Other Medical Staffs

The Medical Staff can be included in a unified medical staff of any health system in which the Hospital participates only after:

(a) Six months' prior written notice to all Medical Staff Members describing the proposed unification, setting forth its risks, benefits, and effects to the Medical Staff and its members;
(b) The Medical Executive Committee concurs [based on favorable recommendations from two-thirds of all Departments reported to the Medical Executive Committee,] following review and study; and
(c) No less than two-thirds of all Medical Staff Members with voting rights who hold clinical privileges to practice on-site at the hospital cast votes in favor of unification. The Medical Executive Committee shall determine whether the Medical Staff votes:
   (i) at a special meeting called for that purpose, or
   (ii) via confidential mail or electronic balloting.

If all these requirements are not met, the Medical Staff shall remain separate from any System unified hospital and continues as the Medical Staff of the Hospital.

If the Medical Staff votes to accept unification, these Medical Staff Bylaws will remain in effect as to the Members, until the Medical Staff Bylaws are amended or new Medical Staff Bylaws are adopted pursuant to the terms of these Bylaws.

(2) Disunification From Other Medical Staffs

The Medical Staff shall disunify from any system-unified medical staff by vote to disunify by two-thirds of all Medical Staff Members with voting rights who hold clinical privileges to practice on-site at the hospital. The Medical Staff shall be the unique Medical Staff of the Hospital effective immediately, operating under the Medical Staff Bylaws in effect immediately prior to unification. Special election shall be called to elect officers, department chairs and other medical staff leadership immediately consistent with the Medical Staff Bylaws in effect immediately prior to unification.

(3) Unification/Disunification Effect on Bylaws

(a) A vote by the Medical Staff to accept a unified medical staff shall have no effect on the application of these Medical Staff Bylaws, which shall continue to govern this Medical Staff and be upheld by the Governing Body. Peer review and other activities of the Medical Staff and its Members shall continue to be governed by [name of state licensing the Hospital] law by which the Hospital is licensed.
(b) Upon disunification, the Medical Staff Bylaws in effect the date of unification shall return to full force and effect.

2. Note that a super-majority for unification purposes cannot exceed the majority level set for medical staff bylaws amendments, as stated in the CMS State Operations Manual, Appendix A.
3. Per the CMS State Operations Manual, Appendix A, only those individuals who “hold privileges to practice at the hospital and actually do practice on-site, and not just via telemedicine” are permitted to vote on unification/disunification. Note that this language will also preclude voting by other categories of medical staff members who hold no clinical privileges (e.g., no-volume community physicians, emeritus members, etc.), even if they have voting rights under the existing bylaws.
Individual responsible for the medical staff

Under the new regulations, CMS requires that the governing body “Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee” (Title 42 §482.12(10), emphasis added). It is vital to the self-governance interests of the medical staff that this “individual” be the elected president or chief of the medical staff, and not a hospital-appointed physician administrator such as a chief medical officer, vice president of medical affairs, etc.

The following medical staff bylaws language, designed to be added to the section delineating the medical staff president/chief of staff duties, seeks to ensure that the governing body consults with the appropriate representative of the medical staff. The language also seeks to ensure that these consultations provide appropriate opportunity for the medical staff and the governing body to work collaboratively to improve the quality and safety of care provided to patients by the hospital.

Sample bylaw: Individual responsible for the medical staff

The President [Chief of Staff] elected by the Medical Staff pursuant to these Medical Staff Bylaws shall:

(1) Serve as the individual responsible for the organization and conduct of the Medical Staff, with whom the Governing Body shall directly consult on all matters related to the quality of medical care provided to patients at the Hospital and other matters of mutual concern at each Governing Body meeting and otherwise as frequently as deemed helpful by the Governing Body, the President/Chief of Staff, or the Medical Staff;

(2) Provide continual consultation directly to the Governing Board as he/she determines warranted by the scope and complexity of Hospital services and the specific patient populations served by a Hospital;

(3) Work with the Governing Board to discuss and collaboratively resolve issues of patient safety and quality of care identified by the hospital's quality assessment and performance improvement program or the medical staff, including at a minimum:
   (a) hospital-wide systemic deficiencies
   (b) system-wide opportunities for quality improvement
   (c) achievable goals for improved community health; and
   (d) Serve on the [Physicians' Council] [Physicians’ Advisory] [Medical Staff Leadership Panel][any other standing or ad hoc Hospital committee or process not elected or established by the Medical Staff which purports to inform the Board or Hospital Administration on the quality of patient care and other medical staff issues].
Sample bylaw: Job description for “individual assigned the responsibility for the organization and conduct of the hospital’s medical staff”

In addition to the bylaws language presented above, the medical staff may wish to develop a “job description” outlining the qualifications, responsibilities, and expectations of the “individual assigned responsibility for the organization and conduct of the hospital’s medical staff,” which may or may not be incorporated into the medical staff bylaws:

(1) Qualifications
   (a) Physician [dentist] [podiatrist] member of the Medical Staff
   (b) Currently serve as the elected Medical Staff President/Chief of Staff
   (c) Is not employed by the hospital as a medical director/vice president of medical affairs

(2) Responsibilities
   (a) Attend all Governing Body meetings, present medical staff quality data and other information of mutual concern, and offer consultation on the quality of patient care at the hospital at each meeting
   (b) Provide continual consultation directly to the Governing Board as he/she determines warranted by the scope and complexity of hospital services and the specific patient populations served by the hospital
   (c) Collaborate with the Governing Board to discuss and resolve issues of patient safety and quality of care identified by the hospital’s quality assessment and performance improvement program or the medical staff, including at a minimum:
      (i) hospital-wide systemic deficiencies
      (ii) system-wide opportunities for quality improvement
      (iii) achievable goals for improved community health
   (d) Serve on the [Physicians’ Council] [Physicians’ Advisory] [Medical Staff Leadership Panel] [any other standing or ad hoc hospital committee or process not elected or established by the medical staff which purports to inform the Board or Hospital Administration on the quality of patient care and other medical staff issues]
   (e) Designate an appropriate Medical Staff representative to attend Governing Body meetings, serve on committees or other collaborative bodies, in his/her absence or as warranted to fulfill the medical staff’s responsibility for quality patient care

(3) Reporting
   (a) Report to the Medical Executive Committee all Governing Body consultations and communications
   (b) Report to the Medical Staff regarding Governing Body consultations at each Medical Staff meeting

---

4. “The responsibility for organization and conduct of the medical staff must be assigned only to one of the following: (i) An individual doctor of medicine or osteopathy; (ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located; (iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.” 42 CFR §482.22 (b)(3).

5. The governing body must: … Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital’s medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital. …” 42 CFR §482.12 (a)(10). In comments, CMS states “we would expect these consultations to occur at least twice during either a fiscal or calendar year …” 79 Fed. Reg. 27112 (May 12, 2014).

6. CMS comments “… we would expect a hospital (or multi-hospital system) governing body to determine the number of consultations needed based on various factors specific to a particular hospital. These factors would include, but are not limited to, the scope and complexity of hospital services offered, specific patient populations served by a hospital, and any issues of patient safety and quality of care that a hospital’s quality assessment and performance improvement program might periodically identify as needing the attention of the governing body in consultation with its medical staff. We also stated that we would expect to see evidence that the governing body is appropriately responsive to any periodic and/or urgent requests from the individual responsible for the organized medical staff of the hospital (or his or her designee) for timely consultation on issues regarding the quality of medical care provided to patients of the hospital.” 79 Fed. Reg. 27112 (May 12, 2014).
Appendix: Relevant Conditions of Participation

- View the Conditions of Participation in full.
- View the CMS State Operations Manual, Appendix A.

Title 42 §482.12 - Condition of participation: Governing body.

(a) Standard: Medical staff. The governing body must:

(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital. For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements of this paragraph (a).

Title 42 §482.22 - Condition of participation: Medical staff.

(b)(4) If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

(i) The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which 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 after a majority vote by the members to maintain a separate and distinct medical staff for their hospital;

(iii) The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

© 2014 American Medical Association. All rights reserved. This document may only be copied, modified, or disseminated for non-commercial purposes. It is for informational purposes only and not intended to replace or serve as legal advice. The laws of individual states will vary. Users with questions are encouraged to consult a knowledgeable medical staff attorney.