
CMS Manual System

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Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 122

Date: September 26, 2014

SUBJECT: Revisions to State Operations Manual (SOM), Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: We are revising Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals to reflect recent regulation changes concerning the Governing Body and Medical Staff Conditions of Participation. We are also taking this opportunity to make clarifications and updates to existing guidance.

NEW/REVISED MATERIAL - EFFECTIVE DATE: September 26, 2014

IMPLEMENTATION DATE: September 26, 2014

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:)

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/A-0043/§482.12 -Condition of Participation: Governing Body
R	Appendix A/A-0045/§482.12(a)(1) - Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;
N	Appendix A/A-0053/§482.12(a)(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).
R	Appendix A/A-0338/§482.22/Condition of Participation: Medical Staff

R	Appendix A/A-0339/§482.22(a) -Standard: Eligibility and Process for Appointment to Medical Staff
R	Appendix A/A-0341/§482.22(a)(2) -The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.
R	Appendix A/A-0347/§482.22(b) Standard: Medical Staff Organization and Accountability
N	Appendix A/A-0348/§482.22(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:....
N	Appendix A/A-0349/§482.22(b)(4)(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;
N	Appendix A/A-0350/§482.22(b)(4)(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;
N	Appendix A/A-0351/§482.22(b)(4)(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....
N	Appendix A/A-0352/§482.22(b)(4)(iv) -The unified and

	<p>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.</p>
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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2014 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

A-0043

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

§482.12 Condition of Participation: Governing Body

There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

Interpretive Guidelines §482.12

The hospital must have a governing body which is effective in carrying out its responsibilities for the conduct of the hospital. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are legally responsible for the conduct of the hospital operations.

If the hospital is part of a healthcare system that includes several separately certified hospitals, each with its own Medicare provider agreement and CMS Certification Number, the governing body of the healthcare system has the option to act as the governing body of each separately certified hospital, unless doing so would conflict with State law. A hospital system also has the option to form several governing bodies, each of which is responsible for several separately certified hospitals. For example, a health system operating hospitals in many States might choose to form regional sub-boards each responsible for the hospitals in its region, or a health system that has a mixture of types of hospitals may choose to form one sub-board responsible for its short-term acute care hospitals and another for its long term care hospitals.

When deciding whether or not to exercise the option to have a single governing body for multiple hospitals in the system, another factor for systems to consider might be Medicare payment requirements at §§412.22(e) - (h) applicable to certain types of hospitals, i.e., non-grandfathered Hospitals-within-Hospitals and Hospital Satellites. In such cases where the hospital system owns both the tenant and the host hospital, using a single governing body for both hospitals would jeopardize the payment status of a hospital that is being paid by Medicare under a payment system excluded from the Hospital Inpatient Prospective Payment System (IPPS). However, surveyors do not assess compliance with or enforce the Medicare payment regulations that govern Hospitals-within-Hospitals or Hospital Satellites.

The Medicare program offers hospital facilities considerable flexibility regarding how they choose to participate. Based on the geographic and other institutional limitations set out in the “provider-based” regulation at §413.65, which addresses provider-based status for hospital facilities in multiple locations, hospital governing bodies make business decisions about how they want to participate in Medicare, and they indicate on their Medicare enrollment application the choices they have made. It is not uncommon to find multiple hospital campuses with one owner located in the same geographic area enrolled

in Medicare as one hospital. It is also not uncommon to see a hospital system choosing to enroll its various facilities as separately certified hospitals. Various factors enter into consideration when the governing body of a system makes these decisions.

For example, some governing bodies prefer to enroll various campuses as separate hospitals, out of a concern that problems at one hospital's campus might jeopardize the Medicare participation of the other campuses if they were a multi-campus hospital covered under one Medicare provider agreement. In other cases a governing body may see the benefits of integrating clinical services on multiple campuses into one integrated hospital. In still other cases, the deciding factor might be the implications for Medicare reimbursement of graduate medical education, the ease of adding satellite locations, etc.

CMS defers to the governing bodies of hospitals to weigh the pertinent factors *and* permissible options, and to make business decisions in their best interest when applying to participate in Medicare. CMS's hospital certification decisions and issuance of a provider agreement and associated CCN follow from these business decisions by a hospital's governing body. But once the "hospital," with whatever component parts, has been certified, that hospital must *independently* demonstrate its compliance with the CoPs, independent of any other facility. (77 FR 29040, May 16, 2012)

If a hospital system has chosen to have a one body act as the governing body for multiple separately certified hospitals (i.e., a system governing body), this does not alter the fact that each hospital must *independently* demonstrate compliance with the CoPs. Examples of what this means include, but are not limited to, the following:

- Each separately certified hospital must be separately and independently assessed for its compliance with the CoPs, through either State Survey Agency or approved *Medicare hospital* accreditation program surveys. There is no survey of a hospital "system," since the Medicare provider agreement and its terms are specific to each certified hospital.
- A system governing body may wish to adopt identical policies and procedures for many aspects of a hospital's operations across all of its hospitals within the system. It has the flexibility to do so, but the documentation of such policies and procedures must be clear that the governing body has chosen to apply them to specifically named hospitals. Also, each hospital must be able to present for inspection the system governing body policies and procedures that clearly apply to that hospital. For example:

A document that says "XX Healthsystem has adopted the following policy" is **not** acceptable. Instead, the document must be more specific, such as, "XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital C." Furthermore, the names of each hospital (Hospitals A, B, and C in this example) must correspond to the names used for their provider agreements. For example, if Hospital C is one Medicare-certified hospital with two inpatient campuses, one called "East" and one called "West," it is **not**

acceptable for the policy document to state, “XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital East and Hospital West.” It would be acceptable to state, “XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital C.”

It also is **not** acceptable for the policy document to state, “XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital East, but not Hospital West.” Since “Hospitals” East and West refer to separate campuses of Hospital C, which participates in Medicare as one multi-campus hospital, it is not appropriate to refer to these separate campuses of C as “hospitals,” since the XX Healthsystem made a business decision to enroll them as parts of one multi-campus hospital in Medicare. CMS recognizes that, depending on the particular policy topic, it may be acceptable to have policies that vary by type of unit/department within a hospital. The system governing body could achieve this as follows: “XX Healthsystem adopts the following policy and procedure requiring that a physician be on-site 24 hours per day, seven days per week on the inpatient campuses of Hospital A and Hospital B, but within Hospital C, only for the East inpatient campus.”

- Likewise, the minutes of the governing body must be written in such a manner so that it is clear when the governing body has taken actions that apply to a specific certified hospital.
- Departments of separately certified hospitals with one system governing body cannot be operationally integrated. For example, if a system has chosen to operate three separately certified hospitals in relatively close proximity to each other rather than to have them certified as one multi-campus hospital, then each hospital must have its own nursing service. It may not have one integrated nursing service with one Director of Nursing who manages one nursing staff for all three hospitals. *The system cannot maintain one integrated schedule that assigns nursing staff among the different hospitals. The system also cannot move them back and forth between hospitals on an ad hoc, as needed basis, as if they were one hospital.*

On the other hand, the policies and procedures the governing body has adopted for the nursing service in each hospital may be identical, *so long as* the services operate separately. It is also permissible for the same individual to be the Director of Nursing for each hospital, provided that he or she is able to carry out all of the duties of the position in each hospital, *such as managing each hospital's separate nursing staff. It is also permissible for one nurse to work at multiple hospitals within the system, in the same way that a nurse may work for multiple hospitals that do not share ownership, but the nurse must have separate work schedules for each hospital. Such schedules cannot overlap.*

- Likewise, although the system may choose to operate a quality assessment/performance improvement (QAPI) program at the system level which standardizes indicators measured across system hospitals, each separately-certified

hospital in the system must have a QAPI program that is specific to that hospital. This is required not only to demonstrate compliance, but also for the governing body to function effectively, since reviewing QAPI program results only at the system level would make it difficult for the governing body to identify and act upon problems that are localized to one hospital.

For example, the system may choose to use the same quality indicators or the same methodology to track adverse events across all system hospitals. But each certified hospital must have its own QAPI data with respect to these indicators and adverse events. If a system is tracking readmission rates across all of its hospitals, it must be able to separate out the hospital-specific results for the governing body's review and possible action.

The governing body must be functioning effectively and holds the ultimate responsibility for the hospital's compliance not only with the specific standards of the governing body CoP, but also with all of the CoPs. This is the case regardless of whether the regulatory text for a particular condition or standard within a condition specifically mentions responsibilities of the governing body. Substantial, i.e., condition-level, non-compliance with one of the other hospital CoPs may be an indicator that the governing body is not functioning effectively. However, it is not the policy of CMS that condition-level noncompliance with any other CoP automatically results in a condition-level citation of the governing body CoP. Surveyors must consider whether the manner and degree of the other deficiencies provide sufficient evidence to conclude that the governing body is not functioning effectively.

Survey Procedures §482.12

- Verify that the hospital has an organized governing body or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.
- If the hospital is part of a hospital system which uses one governing body for several of the hospital's separately certified within the system:
 - Review the governing body minutes to determine if it is clear which actions pertain to which hospitals.
 - Select for review several policy and procedure documents adopted by the system governing body to determine if it is clear that they apply to the hospital being surveyed.

A-0045

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

[The governing body must:]

§482.12(a)(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

Interpretive Guidelines §482.12(a)(1)

The governing body must determine, in accordance with State law, which categories of practitioners are eligible for appointment to the medical staff.

Physicians

The medical staff must, at a minimum, be composed of doctors of medicine or doctors of osteopathy. In addition, the medical staff may include other types of *practitioners* included in the definition of a physician in Section 1861(r) of the Social Security Act:

- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry; and
- a Chiropractor.

In all cases, the *practitioner* included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act and regulations attach further limitations as to the type of hospital services for which a *practitioner* may be considered to be a “physician.” See 42 CFR 482.12(c)(1) for more detail on these limitations.

The governing body has the flexibility, *consistent with State law*, to determine whether *practitioners* included in the definition of a physician other than a doctor of medicine or osteopathy are eligible for appointment to the medical staff.

For Information Only – Not Required/ Not to be Cited

CMS expects that all physician practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital’s medical staff to certain categories of practitioners, e.g., only MDs or DOs, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for other categories of physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

For physician practitioners granted privileges only, the hospital's governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those other physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Non-physician practitioners

Furthermore, the governing body has the authority, in accordance with State law, to *grant medical staff privileges and membership to non-physician practitioners. The corresponding regulation at 42 CFR 482.22(a) allows hospitals and their medical staffs to take advantage of the expertise and skills of all types of practitioners who practice at the hospital when making decisions concerning medical staff privileges and membership. Granting medical staff privileges and membership to non-physician practitioners is an option available to the governing body; it is not a requirement.*

For Information Only – Not Required/ Not to be Cited

CMS expects that all practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital's medical staff to certain categories of practitioners, e.g., only physician practitioners, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for those specific categories of non-physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

For non-physician practitioners granted privileges only, the hospital's governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those non-physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Practitioners are *described* in Section 1842(b)(18)(C) of the Act as *any of the following*:

- Physician assistant (*as defined in Section 1861(aa)(5) of the Act*);
- Nurse practitioner (*as defined in Section 1861(aa)(5) of the Act*);
- Clinical nurse specialist (*as defined in Section 1861(aa)(5) of the Act*);
- Certified registered nurse anesthetist (*as defined in Section 1861(bb)(2) of the Act*);
- Certified nurse-midwife (*as defined in Section 1861(gg)(2) of the Act*);

- Clinical social worker (*as defined in* Section 1861(hh)(1) of the Act);
- Clinical psychologist (*as defined in* 42 CFR 410.71 for purposes of Section 1861(ii) of the Act);
- *Anesthesiologist's Assistant (as defined at §410.69);* or
- Registered dietician or nutrition professional.

Other types of licensed healthcare professionals have a more limited scope of practice and *usually* are not eligible for hospital medical staff privileges, unless their permitted scope of practice in their State *makes them more comparable to the above listed types of non-physician practitioners. Some examples of types of such licensed healthcare professionals who might be eligible for medical staff privileges, depending on State law and medical staff bylaws, rules and regulations include, but are not limited to:*

- *Physical Therapist (as defined at §410.60 and §484.4);*
- *Occupational Therapist (as defined at §410.59 and §484.4); and*
- *Speech Language Therapist (as defined at §410.62 and §484.4).*

Furthermore, some States have established a scope of practice for certain licensed pharmacists who are permitted to provide patient care, services that make them more like the above types of non-physician practitioners, including the monitoring and assessing of patients and ordering medications and laboratory tests. In such States, a hospital may grant medical staff privileges to such pharmacists and/or appoint them as members of the medical staff. There is no standard term for such pharmacists, although they are sometimes referred to as "clinical pharmacists."

Practitioners may be granted active, courtesy, emergency, temporary, etc. membership or privileges in accordance with state law and as specified in the medical staff bylaws, rules, and regulations.

Survey Procedures §482.12(a)(1)

Review documentation and verify that the governing body has determined and stated the categories of physicians and practitioners that are eligible candidates for appointment to the medical staff or *to be granted* medical staff privileges.

A-0053

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

[The governing body must:]

§482.12(a)(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).

Interpretive Guidelines §482.12(a)(10)

In accordance with §482.22(b)(3), there must be an individual member of the hospital's medical staff who is assigned responsibility for the organization and conduct of the medical staff (for purposes of this guidance, the "leader" of the medical staff). §482.12(a)(10) requires that the governing body consult with this individual, or with someone the leader of the medical staff has designated.

"Direct consultation" means that the governing body, or a subcommittee of the governing body, meets with the leader(s) of the medical staff(s), or his/her designee(s) either face-to-face or via a telecommunications system permitting immediate, synchronous communication. (79 FR 27113, May 12, 2014)

This regulation does not preclude a hospital from having a member of the medical staff serve as a member of the hospital's governing body. However, membership on the governing body by a medical staff member is not sufficient per se to satisfy the requirement for periodic consultation. In such a situation the hospital meets the consultation requirement only if the medical staff member serving on the governing body is the leader of the medical staff, or his or her designee, and only if such membership includes meeting with the board periodically throughout the fiscal or calendar year and discussing matters related to the quality of medical care provided to patients of the hospital. If there were a change in the medical staff leadership or his/her designee, and the bylaws governing terms and conditions of governing body membership did not allow for substitution of the new leader of the medical staff (or his or her designee) on the governing body, then the governing body would be expected to engage in direct consultation with the new leader of the medical staff, or his or her designee.

It should be noted that if a hospital chooses to have the leader of the medical staff, or his or her designee, serve on the governing body, there is nothing in the regulation which prohibits the hospital from also including other medical staff members on the governing body in addition to the leader of the medical staff, or his or her designee.

In the case of a multi-hospital system that has one single governing body, the governing body must consult with each separately certified hospital's medical staff leader, or his/her designee. The consultations do not have to be separate. For example, the system governing body could periodically have a meeting that includes the leader of the medical staff, or his/her designee, from each hospital within the system, so long as there is

discussion of matters related to the quality of medical care provided to the patients of each hospital.

If the medical staff members at separately certified hospitals in a multi-hospital system and the hospital system's governing body also have opted to have a unified medical staff (see guidance for §482.22(b)(4)) for some or all of the hospitals in the system, then the governing body must consult with the leader of the unified medical staff or his/her designee. In this case, the leader of the unified medical staff, or the designee, as applicable, is expected to be aware of the concerns/views of members of the medical staff practicing at each separately certified hospital using the unified medical staff.

It is up to the governing body as to whether the leader of the medical staff must make the designation in writing when he or she chooses to designate another individual for these periodic consultations, or whether the leader of the medical staff may make informal, ad hoc designations. It is also up to the governing body as to whether it wishes to establish minimum advance notice of a designation from the leader of the medical staff to the governing body.

The requirement for the governing body to consult periodically throughout the year leaves some flexibility for the governing body to determine how often during the year its consultations with the leader of the medical staff or designee would occur, but it is expected that consultations occur at least twice during either a calendar or fiscal year. ("Fiscal year" refers to the Medicare cost-reporting year for the hospital; in the case of a hospital system with multiple, separately certified hospitals that have one single governing body and a unified medical staff, it is possible that individual hospitals have separate fiscal years. In this case, it would be more practical for the governing body to use a calendar year basis for determining the frequency of consultation.)

The governing body is expected to determine the number of consultations needed based on various factors specific to the hospital, or to each of the hospitals within a multi-hospital system. These factors 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. The hospital must also provide evidence that the governing body is appropriately responsive to any periodic and/or urgent requests from the leader of the medical staff or designee for timely consultation on issues regarding the quality of medical care provided to patients of the hospital. (79 FR 27112, May 12, 2014).

The "year" referenced in the regulation may be either the calendar year or the hospital's fiscal year, as identified on its Medicare cost report. It is up to the hospital which approach it will take, but it must document the approach selected and consistently apply it. For example, if a hospital chooses to use the calendar year, and had only one consultation during a calendar year, it could not then point out that it had had two meetings during the time period covered by its fiscal year.

The required consultation must include discussion of matters related to the quality of medical care provided to the hospital's patients, or, in the case of a hospital system with one single governing body and a unified medical staff, the quality of medical care provided to each separately certified hospital's patients.

The hospital's governing body must adopt policies and procedures addressing how it implements the requirement for periodic, direct consultation with the leader of the medical staff, or the designee. The hospital must have evidence that the required consultations do take place, such as meeting agendas and lists of attendees, or minutes taken of the discussion, including who was present, etc., and that matters related to the quality of medical care provided to patients of the hospital were discussed.

Survey Procedures §482.12(a)(10)

- *Ask the hospital's CEO how the hospital complies with the requirement for periodic consultations by the governing body with the leader of the hospital's medical staff, or the leader's designee. Can the CEO provide evidence that such consultations have occurred, e.g., meeting agendas and lists of attendees, meeting minutes, etc.*
- *Ask the CEO whether the hospital tracks these consultations by the calendar year or its fiscal year; ask to see a copy of the policy that establishes this.*
 - *Is there evidence that the consultations were "direct?"*
 - *Is there evidence that the governing body met with the medical staff leader or designee at least twice during the previous year?*
 - *Is there evidence that the discussion concerned matters related to the quality of medical care in the hospital?*
- *Ask the leader of the hospital's medical staff, or his/her designee, whether he or she has had meetings with either the whole governing body or a subcommittee of it to discuss the quality of medical care in the hospital.*
 - *Has the leader/designee ever requested a meeting in addition to those regularly scheduled, to discuss a matter of urgent concern to the medical staff? If yes, did the governing body respond by setting up a meeting?*
 - *If the hospital shares a unified medical staff with other separately certified hospitals in a multi-hospital system, the interview with the leader of the medical staff, or designee, may have to be conducted by telephone. Ask the leader/designee how he/she gathers information about the concerns/views of members of the medical staff practicing at the hospital being surveyed about the quality of medical care provided at that hospital.*

A-0338

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

§482.22 Condition of Participation: Medical Staff

The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and *which* is responsible for the quality of medical care provided to patients by the hospital.

Interpretive Guidelines §482.22

The hospital *must* have one medical staff for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). *For example, a multi-campus hospital may not have a separately organized medical staff for each campus. On the other hand, in the case of a hospital system, it is permissible for the system to have a unified and integrated medical staff (hereafter referred to as a “unified medical staff”) for multiple, separately certified hospitals.* The medical staff must be organized and integrated as one body that operates under one set of bylaws approved by the governing body. These medical staff bylaws must apply equally to all practitioners within each category of practitioners at all locations of the hospital and to the care provided at all locations of the hospital. The medical staff is responsible for the quality of medical care provided to patients by the hospital.

Survey Procedures §482.22

Surveyors assess the manner and degree of noncompliance with the standards within this condition to determine whether there is condition-level noncompliance.

A-0339

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

§482.22(a) Standard: *Eligibility and Process for Appointment to Medical Staff*

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

Interpretive Guidelines §482.22(a)

The hospital’s governing body has the responsibility, consistent with State law, including scope-of-practice laws, to determine which types/categories of physicians and, if it so chooses, non-physician practitioners or other licensed healthcare professionals (collectively referred to in this guidance as “practitioners”) may be privileged to provide

care to hospital patients. All practitioners who require privileges in order to furnish care to hospital patients must be evaluated under the hospital's medical staff privileging system before the hospital's governing body may grant them privileges. All practitioners granted medical staff privileges must function under the bylaws, regulations and rules of the hospital's medical staff. The privileges granted to an individual practitioner must be consistent with State scope-of-practice laws.

Physicians:

The medical staff must at a minimum be composed of doctors of medicine or doctors of osteopathy. In addition, the medical staff may include other *types of practitioners* included in the definition in Section 1861(r) of the Social Security Act of a “physician:”

- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry; and a
- Chiropractor.

In all cases, the *practitioner* included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act and regulations attach further limitations as to the type of hospital services for which a *practitioner* may be considered to be a “physician.” See §482.12(c)(1) for more detail on these limitations.

The governing body has the flexibility to determine, *consistent with State law*, whether *practitioners* included in the definition of a physician, other than doctors of *medicine* or osteopathy, are eligible for appointment to the medical staff.

For Information Only – Not Required/ Not to be Cited

CMS expects that all physician practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital's medical staff to certain categories of practitioners, e.g., only MDs or DOs, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for other categories of physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

For physician practitioners granted privileges only, , the hospital's governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those other physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Non-physician practitioners

Furthermore, the governing body has the authority, in accordance with State law, to *grant medical staff privileges and membership* to non-physician practitioners. *The regulation allows hospitals and their medical staffs to take advantage of the expertise and skills of all types of practitioners who practice at the hospital when making recommendations and decisions concerning medical staff privileges and membership.*

For Information Only – Not Required/ Not to be Cited

CMS expects that all practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital's medical staff to certain categories of practitioners, e.g., only physician practitioners, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for those specific categories of non-physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

For non-physician practitioners granted privileges only, the hospital's governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those non-physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Practitioners are *described* in Section 1842(b)(18)(C) of the Act as *any of the following*:

- Physician assistant (*as defined in Section 1861(aa)(5) of the Act*);
- Nurse practitioner (*as defined in Section 1861(aa)(5) of the Act*);
- Clinical nurse specialist (*as defined in Section 1861(aa)(5) of the Act*);
- Certified registered nurse anesthetist (*as defined in Section 1861(bb)(2) of the Act*);
- Certified nurse-midwife (*as defined in Section 1861(gg)(2) of the Act*);
- Clinical social worker (*as defined in Section 1861(hh)(1) of the Act*);
- Clinical psychologist (*as defined in 42 CFR 410.71 for purposes of Section 1861(ii) of the Act*);

- *Anesthesiologist's Assistant (as defined in §410.69); or*
- Registered dietician or nutrition professional.

Other types of licensed healthcare professionals have a more limited scope of practice and *usually* are not eligible for hospital medical staff privileges, unless their permitted scope of practice in their State makes them more comparable to the above types of *non-physician* practitioners. *Some examples of types of such licensed healthcare professionals who might be eligible for medical staff privileges depending on State law and medical staff bylaws, rules and regulations include, but are not limited to:*

- *Physical Therapist (as defined at §410.60 and §484.4);*
- *Occupational Therapist (as defined at §410.59 and §484.4); and*
- *Speech Language Therapist (as defined at §410.62 and §484.4).*

Furthermore, some States have established a scope of practice for certain licensed pharmacists who are permitted to provide patient care services that make them more like the above types of non-physician practitioners, including the monitoring and assessing of patients and ordering medications and laboratory tests. In such States, a hospital may grant medical staff privileges to such pharmacists and/or appoint them as members of the medical staff. There is no standard term for such pharmacists, although they are sometimes referred to as "clinical pharmacists."

Practitioners may be granted *active, courtesy, emergency, temporary, etc. membership or privileges in accordance with state law and as specified in the medical staff bylaws, rules, and regulations.*

Survey Procedures §482.22(a)

- *Ask the hospital and medical staff leadership to describe the categories of practitioners who are members of the medical staff or who may be granted medical staff privileges. Ask for documentation that supports their response.*
- *If the hospital grants medical staff privileges and/or membership to physicians who are not MDs/DOs or to non-physician practitioners, ask the hospital and medical staff leadership to describe the process the hospital uses to ensure that any privileges granted are consistent with State law. Ask for documentation that supports their response.*
- *Ask the hospital and medical staff leadership to describe the process by which they exercise oversight of practitioners granted privileges only.*

A-0341

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

§482.22(a)(2) - The medical staff must examine *the* credentials of *all eligible* candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates *in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.*

Interpretive Guidelines §482.22(a)(2)

There must be a mechanism established to examine credentials of individual prospective members (new appointments or reappointments) by the medical staff. The individual's credentials to be examined must include at least:

- A request for clinical privileges;
- Evidence of current licensure;
- Evidence of training and professional education;
- Documented experience; and
- Supporting references of competence.

The medical staff may not make its recommendation solely on the basis of the presence or absence of board certification, but must consider all of the elements above. However, this does not mean that the medical staff is prohibited from requiring in its bylaws board certification when considering a MD/DO for medical staff membership or privileges; only that such certification may not be the only factor that the medical staff considers.

The medical staff makes recommendations to the governing body for each candidate for medical staff membership/privileges that are specific to type of appointment and extent of the individual practitioner's specific clinical privileges, and then the governing body takes final appropriate action.

Each practitioner who is a member of the medical staff or who holds medical staff privileges is subject to the medical staff's bylaws, rules, and regulations, in addition to all the requirements of the Medical Staff Condition of Participation. The medical staff and the governing body must enforce its medical staff requirements and take appropriate actions when individual members or other practitioners with privileges do not adhere to the medical staff's bylaws, regulations, and rules. They must likewise afford all members/practitioners who hold privileges the protections and due process rights provided for in the bylaws, rules and regulations.

A separate credentials file must be maintained for each individual medical staff member or applicant. The hospital must ensure that the practitioner and appropriate hospital patient care areas/departments are informed of the privileges granted to the practitioner.

Survey Procedures §482.22(a)(2)

- Determine whether the medical staff bylaws identify the process and criteria to be used for the evaluation of candidates for medical staff membership/privileges.
- Determine whether the criteria used for evaluation comply with the requirements of this section, State law, and hospital bylaws, rules, and regulations.
- Determine whether the medical staff has a system to ensure that practitioners seek approval to expand their privileges for tasks/activities/procedures that go beyond the specified list of privileges for their category of practitioner.
- *Ask the leadership of the medical staff what methods are used to ensure that all medical staff members and non-member practitioners who hold privileges adhere to the medical staff bylaws, rules and regulations and are afforded the protections and due process rights provided for under the bylaws, rules and regulations. Ask for specific examples of actions taken.*
- *When interviewing practitioners during the survey, ask how they are made aware of their rights and responsibilities with respect to medical staff bylaws, rules and regulations.*

A-0347

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

§482.22(b) Standard: Medical Staff Organization and Accountability

The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.

- (1) The medical staff must be organized in a manner approved by the governing body.
- (2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.
- (3) 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.

Interpretive Guidelines §482.22(b)(1) – (3)

The conditions of participation create a system of checks and balances within an overall framework of collaboration between the governing body and the medical staff (and, to a certain degree, also between an individual practitioner and the hospital's medical staff and governing body). Each has its own areas of authority. The medical staff has oversight of all practitioners practicing in the hospital through processes such as peer review and making recommendations concerning privileging and re-privileging. The governing body has the authority to establish the categories of healthcare professionals (regardless of the terms used to describe those categories) who are eligible for privileges and medical staff appointment. However, the governing body must rely on the medical staff to apply the criteria for privileging and appointment to those eligible candidates and to make their recommendations before the governing body makes a final decision to appoint or not appoint a practitioner to the medical staff. (77 FR 29042 May 16, 2012).

If the hospital uses a unified medical staff that it shares with other hospitals that are part of a multi-hospital system, this does not change the requirement for the medical staff to be well organized and accountable to the system's governing body for the quality of care in each separately certified hospital.

Leadership of the medical staff

The members of the hospital's medical staff must select, in accordance with the medical staff bylaws, rules or regulations approved by the governing body, a single individual to lead the medical staff and be responsible for the organization and conduct of the medical staff. This individual must be a doctor of medicine or osteopathy, or, if permitted by State law where the hospital is located, a doctor of dental surgery, dental medicine, or podiatric medicine. Removal of the leader of the medical staff may only occur in accordance with medical staff bylaws, rules or regulations.

If the hospital uses a unified medical staff, only one individual may be responsible for the organization and conduct of the unified medical staff; that individual may or may not hold privileges and practice at the hospital being surveyed. When the individual does not practice at the hospital being surveyed and it is necessary to interview this individual as part of a survey, a telephone interview must be arranged.

Executive Committee

The medical staff bylaws, rules and regulations may provide for the members of the medical staff to select a smaller executive committee to which it delegates many of the functions of the medical staff, in order to increase the efficiency of its operations. If the medical staff has an executive committee, the majority of the *voting* members must be doctors of medicine (MDs) or osteopathy (DOs).

For Information Only – Not Required/ Not to be Cited

A hospital is not required to have an executive committee. However, use of an executive

committee may facilitate efficient and effective functioning of the medical staff in hospitals systems that use a unified medical staff, particularly if the executive committee includes members from each hospital that shares the unified medical staff.

Accountability of the medical staff

The medical staff must be accountable to the hospital's governing body for the quality of medical care provided to the patients. The medical staff demonstrates its accountability through its exercise of its duties related to appointment of members of the medical staff, its conduct of reappraisals, including peer reviews, its approval of policies and procedures as required under other conditions of participation and its leadership participation in the organization and implementation of the hospital's quality assessment and performance improvement program required in accordance with §482.21.

If the hospital uses a unified medical staff, the medical staff continues to be accountable for the quality of care in each separately certified hospital that uses the unified medical staff.

Survey Procedures §482.22(b)(1) – (3)

- Verify that the medical staff has a formal, organized structure reflected in the medical staff bylaws, rules and regulations and that functions and responsibilities within the medical staff and with respect to the governing body and other parts of the hospital are reflected.
- If there is a medical staff executive committee, verify that a majority of the members are doctors of medicine or osteopathy.
- Verify that an individual doctor of medicine or osteopathy, or if permitted by State law, a doctor of dental surgery, dental medicine, or podiatric medicine, selected by the medical staff, is responsible for the conduct and organization of the medical staff.
- Ask the CEO and medical staff leadership to describe the mechanisms by which the medical staff fulfills its responsibility to be accountable for the quality of medical care in the hospital.
- Interview several members of the medical staff, including both practitioners who hold leadership or executive committee positions and ones who do not. Ask them what their medical staff duties and responsibilities are and how they perform them. Ask them to describe how the medical staff is accountable for the quality of medical care provided to patients.

A-0348

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

§482.22(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:....

Interpretive Guidelines §482.22(b)(4)

A hospital that is part of a system consisting of multiple separately certified hospitals may use a single unified and integrated medical staff (hereafter referred to as a “unified medical staff”) that is shared with one or more of the other hospitals in the system. In other words, as long as the requirements of §482.22(b)(4) are met, it is not necessary for each separately-certified hospital within the system to have its own distinct medical staff organization and structure, including hospital-specific medical staff bylaws, rules and requirements, hospital-specific medical staff leadership, hospital-specific credentialing and peer review, etc. Instead, it may use one medical staff organization and structure for multiple hospitals, so long as all of the requirements of this section are met. However, separately certified hospitals which share a single unified and integrated medical staff must also share a system governing body, in accordance with the provisions of §482.12, since only one governing body may carry out the governing body’s medical staff responsibilities for a unified medical staff.

Note that a multi-campus hospital that has several inpatient campuses that are provider-based, remote locations of the hospital is not a multi-hospital system. A multi-campus hospital is one certified hospital, not several separately certified hospitals. A multi-campus hospital may not have separate medical staffs at each campus, since each hospital must have no more than one medical staff. A multi-campus hospital with one medical staff separate from that of other certified hospitals is not employing a unified medical staff as that term is used in this regulation. However, a multi-campus hospital that is part of a hospital system consisting of multiple separately certified hospitals may share a unified medical staff with other separately certified hospitals within the system.

It should also be noted that a hospital system that includes certain types of hospitals, i.e., Hospitals-within-Hospitals or Hospital Satellites, that are being paid under a Medicare payment system other than the Hospital Inpatient Prospective Payment System (IPPS) might jeopardize the Medicare payment status of those excluded hospitals if it owns both the tenant and host hospitals and uses a unified medical staff for both. This is the case even if the requirements of §482.22(b)(4) are met. However, surveyors do not assess compliance with or enforce the Medicare payment regulations that govern Hospitals-within-Hospitals or Hospital Satellites.

When granting practitioners privileges to provide patient care, a hospital's governing body must specify those hospitals in the system where the privileges apply, since, in addition to the qualifications of individual practitioners, the services provided at each hospital must be considered when granting privileges. For example, psychiatric hospitals do not offer surgical services, labor and delivery services, nuclear medicine, etc., so it would not be appropriate for practitioners practicing in these areas to hold privileges at psychiatric hospitals in a multi-hospital system that uses a unified medical staff. Likewise if a multi-hospital system covers a wide geographic area, many of its practitioners may have no interest in practicing on site at hospitals that are distant from their usual practice location(s). In addition, in order for the acceptance or opt-out provisions of §482.22(b)(4)(i) and (ii) to be workable, privileges must be granted on a hospital-specific basis to practitioners who actually practice or are likely to practice at the hospital.

The governing body in a multi-hospital system must elect to exercise this option. Since a number of hospital systems interpreted the Medical Staff CoP to permit a unified and integrated medical staff prior to publication of the final rule at §482.22(b)(4) on May 12, 2014 or its effective date on July 11, 2014, the existence of a unified medical staff prior to July 11, 2014 is considered evidence of the hospital's governing body's election of this option.

- This does not relieve the governing body of the responsibility to conduct a review of all applicable State and local laws, including regulations, and make a determination that use of a unified medical staff that is shared by multiple hospitals does not conflict with those laws. The hospital must maintain documentation of this determination by its governing body.*
- Nor does it relieve the governing body of the obligation to inform the medical staff of the right to vote to opt out of a unified medical staff arrangement. (See discussion of §482.22(b)(4)(ii), which requires notification of all members of this right. Failure to comply would be cited under the tag for §482.22(b)(4)(ii).)*

If a hospital is part of a multi-hospital system that wishes to establish a unified medical staff for some or all of its separately certified hospitals after the July 11, 2014 effective date of the final rule at §482.22(b)(4), then the hospital's system governing body must document in writing its decision to elect to use the unified medical staff option, conditioned upon acceptance of a unified medical staff by the hospital's medical staff in accordance with §482.22(b)(4)(i). The governing body must also document its determination that such election does not conflict with State or local laws, including regulations.

Surveyors are not expected, as part of their assessment of compliance with the Medicare CoPs, to evaluate whether the governing body's determination of compliance with State and local law is accurate. This would be handled by the appropriate State or local authorities, or, if the State Survey Agency is the appropriate authority, under its State licensure or other authority and not as part of a Federal survey.

Survey Procedures §482.22(b)(4)

- *Ask the hospital and medical staff leadership if the hospital is part of a multi-hospital system of separately certified hospitals. If yes, ask if the hospital also shares its governing body and medical staff with one or more other separately-certified hospitals in the system.*
 - *If yes:*
 - *Does the use of the unified medical staff predate July 11, 2014? If yes, ask for documentation of the governing body's determination that use of a unified medical staff does not conflict with State or local law.*
 - *Did the use of the unified medical staff start after July 11, 2014? If yes, ask for documentation of the governing body's decision to elect use of a unified medical staff and of its determination that use of a unified medical staff does not conflict with State or local law.*
 - *Can the hospital produce documentation that practitioners who practice at the hospital have been granted privileges by the hospital's governing body that specify the practitioner's privileges apply to specific hospital(s), which include the hospital being surveyed?*

A-0349

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

[§482.22(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;

Interpretive Guidelines §482.22(b)(4)(i)

The decision for a particular certified hospital in a multi-hospital system to use a unified medical staff is a joint one arrived at by the:

- *Election of the unified medical staff option by the hospital's governing body; and*

- *Acceptance by a majority of the medical staff members who hold privileges to practice at that particular hospital, voting in accordance with the medical staff bylaws.*

The medical staff of each hospital also has the option to opt out of an existing unified medical staff, when a majority of the medical staff members who hold privileges to practice at that particular hospital, voting in accordance with the medical staff bylaws, vote to do so.

For purposes of voting on whether to accept or opt out of a unified medical staff, the term “privileges to practice at that particular hospital” is interpreted to mean only those practitioners who hold privileges to practice on-site at the hospital. Practitioners who hold only telemedicine privileges at a hospital are not to be included when identifying which practitioners are eligible to vote nor what constitutes a majority of the practitioners holding privileges at the hospital.

A hospital that is part of a hospital system is expected to have medical staff bylaws, rules and requirements that address the regulatory requirements of §482.22(b)(4)(i) – (iv) related to using a unified medical staff, including the processes under the bylaws for voting to accept or opt out of a unified medical staff. This is the case even if the hospital currently does not use a unified medical staff.

If the hospital uses a unified medical staff, depending on State law requirements, the unified medical staff bylaws, rules and requirements required at §482.22(b)(4)(ii) may substitute for hospital-specific medical staff bylaws, rules and requirements. However, CMS recognizes that the process of amending bylaws can be a lengthy one. Hospitals that were part of a hospital system using a unified medical staff as of July 11, 2014 are expected to have initiated the process before December 31, 2014 to effect the necessary amendments, even if the process is not completed until after that date. Likewise, when a hospital is acquired by a system but maintains separate participation in Medicare, if the hospital’s governing body elects to use a unified medical staff and the medical staff accepts such election, the hospital is expected to initiate the necessary changes to its medical staff bylaws, rules and requirements no later than six months after the effective date of its acquisition.

In establishing medical staff bylaws governing medical staff voting on the questions of acceptance of, or opting out of, a unified medical staff, the medical staff and the governing body, which must approve the revised bylaws in accordance with §482.12(a)(4), have the flexibility to determine the details of the voting process, such as how an acceptance or opt-out vote can be requested; whether all categories of members holding privileges to practice on-site at the hospital are afforded medical staff voting rights; whether voting will be in writing and open or by secret ballot, etc. However, a hospital may not set up bylaws that unduly restrict the rights of medical staff members when voting on the issue of accepting or opting out of a unified medical staff structure. For example:

- *Hospitals may not establish different criteria as to which categories of medical staff members have voting rights with respect to a vote to accept or opt out of a unified medical staff than are used for other amendments to the medical staff's bylaws, except as required under the regulation at §482.22(b)(4) that only members holding privileges to practice at the hospital may vote. (See also the discussion below concerning delegation of authority to the medical staff executive committee.)*
- *Hospitals may not require as a condition for holding an opt-out vote that there be a petition signed by the same number of voting members as would be required for a successful vote to opt out.*
- *Hospitals may require for a successful acceptance or opt-out vote a "supermajority", that is, a majority that is greater than a simple majority of more than fifty percent of the medical staff members with voting rights holding privileges to practice at the hospital, so long as the same type of supermajority is otherwise generally required to amend the medical staff's bylaws, rules and requirements.*
- *In the case where a hospital system has a unified medical staff and members of the staff at a hospital in the system exercise their right to hold a vote on the question of opting out, the hospital may not permit delegation of an opt-out decision to the unified medical staff's executive committee. This is the case even when the executive committee is otherwise delegated authority to amend unified medical staff bylaws, rules and requirements that it recommends for approval to the governing body. In cases where the bylaws permit such delegation to the unified medical staff's executive committee for other purposes, a "majority" for purposes of conducting a vote on whether to opt out of a unified medical staff consists of a simple majority, that is, any number which is greater than fifty percent, of the medical staff members practicing at the hospital who have voting privileges.*
 - *On the other hand, in the case where a hospital that is part of a hospital system but has a separate medical staff is holding a vote on whether to accept participating in a unified medical staff, a hospital may permit a vote by members of the hospital's medical staff executive committee only, if this is consistent with the hospital's medical staff bylaws governing amendments in effect at the time of the vote.*
- *A hospital may establish a minimum interval between acceptance or opt-out votes, such as not permitting a vote more than once every two years. However, a minimum interval between votes longer than two years might unduly restrain the rights of the members of the medical staff and would not be permissible.*

It is not expected that the medical staff bylaws, rules and requirements that were in effect as of July 11, 2014 would address the issue of a unified medical staff, nor the process of

voting by medical staff members at each hospital to accept or opt out of a unified medical staff. Although it is expected that the medical staff bylaws, rules and requirements of hospitals that are part of a hospital system will be amended in a timely fashion as discussed above, this does not mean that a vote to accept or opt out of a unified medical staff may not take place prior to enactment of such amendments.

Voting is governed by the hospital's medical staff bylaws in effect at the time of the vote, except that only voting members of the medical staff who hold privileges to practice on-site at that hospital may participate in the vote. With respect to what constitutes a "majority," the provisions of the bylaws governing voting rights and voting procedures at the time of the vote apply. However, as discussed above, in the case of a vote to opt-out of a unified medical staff, the vote may not be delegated to the executive committee of the unified medical staff.

Since a number of hospital systems interpreted the Medical Staff CoP to permit a unified medical staff prior to publication of the final rule at §482.22(b)(4) on May 12, 2014 or its effective date of July 11, 2014, in the case of a hospital's use of a unified medical staff which began prior to the latter date, it is not necessary for the hospital to hold a vote among the members of the medical staff who hold privileges at that hospital to determine whether the majority accepts the continued use of a unified medical staff. However, the governing body is expected to formally notify the medical staff practicing at each hospital of its preference to continue using a unified medical staff arrangement, as well as of the right of the medical staff holding privileges at each hospital to vote to opt out of the unified medical staff.

If the system governing body of a hospital that is part of the multi-hospital system but which has a separate medical staff elects after July 11, 2014 to create a system unified medical staff structure and/or to include the hospital's medical staff in an already existing unified medical staff structure, the hospital must arrange for a vote by medical staff members, in accordance with the medical staff bylaws, on whether or not to accept use of a unified medical staff for their hospital. The hospital may not use a unified medical staff unless a majority of its medical staff members holding voting rights vote, in accordance with the hospital's medical staff bylaws, to accept a unified medical staff.

Even if a majority of a hospital's medical staff has voted to use a unified medical staff in the past, the members of the unified medical staff with voting rights and holding privileges to practice on-site at that hospital still retain the right to hold a vote to opt out of the unified medical staff structure at a future date. If a majority of the staff with voting rights and holding privileges at that hospital vote, in accordance with the unified medical staff's bylaws, to opt out, then the hospital must establish a separate medical staff.

Survey Procedures §482.22(b)(4)(i)

- *Assess compliance with this regulation if the hospital is part of a system that consists of more than one separately certified hospital, regardless of whether it uses a unified*

medical staff at the time of survey or not. (See survey procedures for §482.22(b)(4) above.)

- *If the hospital uses a unified medical staff, ask the hospital's leadership when it began to do so. Is there any documentation to support the response?*
 - *If the hospital began using a unified medical staff after July 11, 2014, is there evidence that a majority of the medical staff holding privileges at the hospital at the time of the vote voted in accordance with medical staff bylaws to accept using a unified medical staff?*
- *If the hospital uses a unified medical staff, do the medical staff bylaws clearly describe a process by which a vote to opt out of using a unified medical staff may be requested and conducted?*
 - *Are there provisions that are described in the guidance above as unduly limiting the rights of medical staff members to vote on whether to accept or opt out of a unified medical staff?*
 - *If there are other requirements in the voting process that appear to limit opt-out voting, ask the medical staff leadership to explain why the limitations are reasonable and not unduly restrictive.*
 - *Ask the hospital and members of the medical staff whether there has ever been a vote on the question of opting out. If yes, ask the hospital to produce evidence that a majority of the practitioners holding privileges at the hospital voted against opting out.*
- *Can the hospital readily identify the medical staff members who are eligible to vote whether to accept or to opt out of a unified medical staff?*

A-0350

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[§482.22(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:]

(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;

Interpretive Guidelines §482.22(b)(4)(ii)

A hospital that uses a unified medical staff must ensure that the unified medical staff has one set of bylaws, rules and requirements that describe the medical staff's processes for self-governance, appointment, credentialing, privileging, oversight, peer review, and due process rights guarantees. Consistent with the requirements for a system governing body in §482.12, the documentation of the bylaws, rules and requirements that apply to the unified medical staff must identify each separately certified hospital that has elected to use a unified medical staff and which, therefore, is covered by the unified medical staff bylaws, rules and regulations. Depending on State law requirements, the unified medical staff bylaws, rules and requirements may be in addition to or instead of hospital-specific medical staff bylaws, rules and requirements. The unified medical staff's bylaws, rules and requirements must not conflict with any of the specific requirements for medical staff found elsewhere in §482.12 or §482.22, or under any other hospital CoPs which assign responsibilities to the hospital's medical staff.

The unified medical staff's bylaws, rules and requirements addressing its self-governance processes must provide for a process by which members of the unified medical staff holding privileges to practice on site at each separately certified hospital are advised that they have the right to vote on whether to opt out of participation in the unified medical staff, and that if a majority vote to opt out, then the hospital must establish a separate medical staff. At a minimum, the hospital must advise medical staff members in writing of their right to vote by majority to opt out when medical staff membership is first granted, and when it is renewed.

The bylaws must address the process by which a vote to opt out of the unified medical staff is conducted. In establishing the unified medical staff bylaws governing opting out, the unified medical staff, and the system governing body, which must approve the medical staff's bylaws, rules or regulations in accordance with §482.12(a)(4), have the flexibility to determine the details of the voting process, such as how an acceptance or opt-out vote can be requested; whether all categories of members holding privileges to practice on-site at the hospital are afforded medical staff voting rights; whether voting will be in writing and open or by secret ballot, etc. However, the unified medical staff and system governing body may not set up bylaws that unduly restrict the rights of medical staff members at each separately certified hospital to vote whether to accept or opt out of a unified medical staff structure. For example:

- *The bylaws, rules and requirements may not establish different criteria as to which categories of medical staff members have voting rights with respect to a vote to accept or opt out of a unified medical staff than are used for any other type of voting the medical staff engages in, except as required under the regulation at §482.22(b)(4) that only members holding privileges to practice at the hospital may vote. (See also the discussion below concerning delegation of authority to the medical staff executive committee.)*
- *The bylaws, rules and requirements may not require as a condition for holding an opt-out vote that there be a petition signed by the same number of voting members as would be required for a successful vote to opt out.*
- *The bylaws, rules and requirements may require for a successful acceptance or opt-out vote a “super-majority,” that is, a majority that is greater than a simple majority of more than fifty percent of the medical staff members with voting rights holding privileges to practice at the hospital, so long as the same type of supermajority is otherwise required to amend the unified medical staff’s bylaws, rules and requirements.*
- *In the case where a hospital system has a unified medical staff and members of the staff at a hospital in the system exercise their right to hold a vote on the question of opting out, the unified medical staff bylaws may not permit delegation of an opt-out decision to the unified medical staff’s executive committee. This is the case even when the executive committee is otherwise delegated authority to amend unified medical staff bylaws, rules and requirements that it recommends for approval to the governing body. In cases where the bylaws permit such delegation to the unified medical staff’s executive committee for other purposes, a “majority” for purposes of conducting a vote on whether to opt out of a unified medical staff consists of a simple majority, that is, any number which is greater than fifty percent of the medical staff members practicing at the hospital who have voting privileges.*
- *The bylaws, rules and requirements may establish a minimum interval between acceptance or opt-out votes, such as not permitting a vote more than once every two years. However, minimum interval between votes longer than two years might unduly restrain the rights of the members of the medical staff and would not be permissible.*

Survey Procedures §482.22(b)(4)(ii)

- *Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for §482.22(b)(4) above)*
- *Ask the hospital’s leadership for evidence that the unified medical staff’s bylaws, rules and requirements are readily available, and that it is clear that they apply to that hospital.*

- *Ask the hospital's leadership to provide evidence that the unified medical staff bylaws, rules or requirements address the rights of members holding privileges and voting rights at the hospital to vote to opt out of using the unified medical staff, including notification of these rights.*
- *Ask how the unified medical staff bylaws define a majority for the purpose of an opt-out vote. If the unified medical staff bylaws require a super-majority, ask for evidence that this is consistent with the way "majority" is defined for other amendments to the bylaws.*
- *Do the bylaws, rules or requirements clearly describe how and when voting members holding privileges at the hospital are advised of their rights?*
- *Can the hospital readily identify the members of the unified medical staff practicing at the hospital who are eligible to vote to opt out and therefore must be advised of their rights?*
- *Do the credentialing and privileging files of members of the medical staff have any evidence of their being notified of their right to vote by majority to opt out?*
- *Interview several members of the medical staff to determine if they recall being notified of their right to vote by majority to opt out.*

A-0351

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

[§482.22(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:]

(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....

Interpretive Guidelines §482.22(b)(4)(iii)

The separately certified hospitals belonging to a multi-hospital system and using a single unified medical staff may be very different from each other, presenting different needs and challenges for the medical staff. As a result, the unified medical staff is expected to take these differences into account rather than using a one-size-fits-all approach for all of its policies and procedures. For example, a multi-hospital system may:

- *Consist of a mixture of different types of hospitals, such as short-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, children's hospitals, and*

long-term care hospitals. As a result, they would offer different types of services to different patient populations. This could have implications for medical staff functions such as the periodic review of credentials and privileges and ongoing peer review of the quality of medical care. It could also have implications for other responsibilities the medical staff has under various CoPs. For example, the medical staff has a key role in the development and oversight of the use of standing orders/protocols, but these orders/protocols may need to be specific to each hospital, reflecting the types of services a hospital offers and its patient population;

- Consist of hospitals that differ in size, ranging from comparatively small hospitals in rural areas, or which provide specialized rehabilitation or long term care hospital services, to very large short term acute care service hospitals. Such differences could have implications for various medical staff requirements, such as on-call requirements.*
- Consist of hospitals that differ as to whether they are teaching hospitals or not, which would have implications for policies concerning the roles and supervision of residents.*
- Consist of hospitals that are located in different states which have different licensure requirements affecting the organization and composition of the medical staff. For example, in one state it might be permissible for non-physician practitioners to be members of the medical staff, while in another the medical staff is limited to physicians.*

On the other hand, a multi-hospital system may have a conscious strategy of having hospitals that are very similar to each other in terms of size, services, patient populations served, and type of location. In this case, the unified medical staff would have fewer challenges in addressing the needs of each hospital, and might have more policies that are uniform across the medical staff.

In all cases the hospital's leadership and the medical staff leadership must be able to explain how the way in which the unified medical staff is organized and functions takes account of and responds to the unique circumstances of the hospital that is being surveyed.

Survey Procedures §482.22(b)(4)(iii)

- Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for §482.22(b)(4) above)*

- *Ask the hospital's and medical staff's leadership to describe the other types of hospitals in the system with which it shares a unified medical staff, and how the hospital's unique circumstances are addressed. For example, how does the unified medical staff assure that:*
 - *Standing orders it has approved are also approved by the nursing and pharmacy leadership in each separately certified hospitals? (see §482.24(c)(3)(i));*
 - *Policies and procedures developed by the medical staff to minimize drug errors, if this function has not been delegated to the hospital's pharmaceutical service, take into account any unique hospital circumstances? (see §482.25);*
 - *The formulary system established by the medical staff takes into account any unique hospital circumstances? (See §482.25(b)(9));*
 - *The medical staff's specification of procedures and treatments requiring a properly executed informed consent reflects any unique hospital circumstances? (see §482.24(c)(4)(v));*
 - *The medical staff carries out its joint responsibility with the CEO and Director of nursing for ensuring that hospital-specific infection control problems identified by the hospital's infection control officer(s) are addressed in the hospital's QAPI and training programs? (see §482.42(b));*
 - *The medical staff fulfills its joint executive responsibilities, along with the hospital's governing body and administrative officials, for ensuring that the hospital-specific QAPI program is:*
 - *Ongoing, defined, implemented and maintained;*
 - *Addresses hospital-specific priorities for improved quality of care and patient safety, and that all improvements are evaluated;*
 - *Establishes clear expectations for safety in the hospital;*
 - *Allocates adequate resources for the hospital-specific QAPI program;*
 - *and*
 - *Determines annually the number of distinct improvement projects conducted in the hospital?**(See §482.21(e))*
 - *Medical staff policies governing ordering of outpatient services address any unique hospital circumstances? (See §482.54(c)(4))*

- *Medical staff policies and recommendations governing which practitioners may be authorized to write orders and be responsible for the care of the patient conform to State law, including scope of practice law, for the State in which the hospital is located? (multiple citations in various CoPs)*

A-0352

(Rev.122, Issued: 09-26-14, Effective: 09-26-14, Implementation: 09-26-14)

[\$482.22(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:]

(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.

Interpretive Guidelines §482.22(b)(4)(iv)

The hospital's unified medical staff must have written policies and procedures that address how it considers and addresses needs and concerns expressed by members who practice at the hospital. This provision is not about an individual medical staff member's concerns with privileges granted or not granted to him/her, peer review results, due process issues, etc., since these matters are addressed under the requirements at §482.22(a) and (c) as well as §482.22(b)(4)(ii). Instead, this provision addresses a requirement for the unified medical staff to consider and address concerns that practitioners have concerning their own hospital's needs. For example, physicians practicing in a children's hospital may have concerns about having protocols for medication administration that reflect specific pediatric patient concerns, or physicians practicing in a small rural hospital may have concerns about how to get timely telemedicine consults from their colleagues in urban areas.

The medical staff has flexibility in establishing its written policies and procedures for addressing these local concerns, but at a minimum they must cover the following:

- *A process by which members who practice at a hospital can raise their local concerns and needs with the unified medical staff's leadership;*
- *How members are informed of the process by which they can raise their local concerns and needs;*

- *A process for referring the concerns and needs raised to the appropriate committee or other group within the medical staff for due consideration; and*
- *Documentation of the outcome of the medical staff's review of the concerns and needs raised.*

Survey Procedures §482.22(b)(4)(iv)

- *Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for §482.22(b)(4) above)*
- *Determine that the unified medical staff has policies and procedures addressing how members can raise local concerns and needs. Do the written policies and procedures cover the minimum elements?*
- *Ask the hospital and the medical staff leadership whether any members practicing at the hospital have raised concerns or needs. If yes, ask for documentation on how the concern/need was considered and addressed by the unified medical staff.*
- *Ask members of the medical staff if they are aware they can raise local concerns or needs with the leadership of the unified medical staff.*