commenter recommended that CMS retain § 442.110 and revise it to state that a facility's certification will be automatically cancelled on a specific date unless the State Survey Agency finds that the deficiencies are corrected or sufficient progress has been made and has a new plan for correction that has been accepted.

Response: We agree with the commenter that it is critical to retain the regulatory language which requires that a facility correct cited deficiencies to retain their certification; however, we do not agree that § 442.110 must include a reference to automatic cancellation of certification. In response to this comment, we will retain existing § 442.110 with revisions stating that ICFs/IID may be certified with standard level deficiencies under § 442.101 only if: 1) the survey agency finds that all deficiencies have been satisfactorily corrected; or 2) the survey agency finds that the facility has made substantial progress in correcting the deficiencies and has a new plan of correction that is acceptable.

Contact for ICFs/IID Topics: Martin Kennedy, 410-786-0784.

C. Hospitals

1. Governing Body (§ 482.12)

On May 16, 2012, we published a final rule, entitled "Reform of Hospital and Critical Access Hospital Conditions of Participation" (77 FR 29034). In that rule, we finalized changes to the requirements of the "Governing body" CoP, § 482.12, and adopted a policy to allow one governing body to oversee multiple hospitals in a multi-hospital system. Additionally, we added a requirement for a medical staff member, or members, from at least one hospital in the system to be included on the governing body as a means of ensuring communication and coordination between the governing body and the medical staffs of individual hospitals in the system. After publication of the rule, we received considerable feedback that the mandate requiring medical

staff representation on the governing body of a hospital could cause unanticipated complications for many hospitals. We recognized that the provision to include a member of the medical staff on a hospital's governing body creates conflicts for some hospitals, particularly public and not-for-profit hospitals. Issues include, but are not limited to, potential conflicts with some State and local laws that require members of a public hospital's governing body to either be publicly elected or appointed by the State's governor or by some other State or local official(s).

Given the complexity of the issue, and in light of industry feedback, we reviewed this requirement and gathered the relevant background information on the issues raised by stakeholders. After consideration of the issues, we proposed to rescind part of the new requirement and to propose an alternative. Specifically, we proposed to remove the requirement for a medical staff member, or members, to serve on a hospital's governing body and proposed to add a requirement that the hospital's governing body directly consult with the individual responsible for the organized medical staff (or his or her designee). While we believe that it is important that our requirements avoid any unnecessary conflicts for hospitals, we believe that it is essential that the requirements also ensure that the medical staff perspective on quality of care is heard by a hospital's governing body. Therefore, we proposed to add a new provision to the "Medical staff" standard of the Governing body CoP at § 482.12(a)(10). This new provision would require a hospital's governing body to directly consult with the individual responsible for the organized medical staff of the hospital, or his or her designee. At a minimum, this direct consultation would require a discussion of matters related to the quality of medical care provided to patients of the hospital and must occur periodically throughout the fiscal or calendar year. We indicated in the proposed rule that this proposed language reflects our intention to leave some degree of flexibility for a hospital's governing body (or a multi-hospital system's governing

body) to determine how often during the year its consultations with the individual responsible for the organized medical staff of the hospital (or his or her designee) would occur, and that we would expect these consultations to occur at least twice during either a fiscal or calendar year. Moreover, we indicated in the proposed rule that 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.

Additionally, for a multi-hospital system using a single governing body to oversee multiple hospitals within its system, we proposed to require the single governing body to 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 proposed. In the proposed rule, we stated that we believe this proposal represents the best solution for those hospitals that were unintentionally burdened by the requirement finalized in the May 16, 2012, rule, while still addressing the concerns of many stakeholders who responded to the final rule, many of whom firmly stated their belief that medical staff input on a hospital's governing body is essential to the continuing quality of patient care delivered in the hospital.

We received a total of 83 comments from individuals, medical societies, professional societies, hospital associations, and national organizations on this proposal. The comments reflected a mixed response to our proposal, generally divided between the response of physician and physician groups and hospitals and hospital groups. Here we respond to specific comments:

Comment: Commenters generally asked that CMS retain the requirement for a member of the medical staff to be a member of the governing body and felt that physician representation on the governing body was critical to ensure adequate medical staff input into the quality of medical care provided to hospital patients. Some of these commenters felt that any conflict with state or local laws could be resolved without rescinding the provision requiring a medical staff member to be a member of the governing body. One commenter felt the conflict created by the requirement was overstated.

Response: We appreciate the commenters' concerns. However, as discussed in the preamble to the proposed rule, the existing requirement posed unanticipated complications for many hospitals, especially public and government-owned institutions. We believe it is important to avoid such unnecessary conflicts and complications and that our proposal reflects the most efficient option for doing so. We considered deferring to state and local law as suggested, but remained concerned that such deference would not adequately address and resolve the complications and conflicts that we are addressing. We believe our proposal achieves an appropriate balance between the concerns raised by the commenters and the problems and conflicts created by requiring medical staff membership on the governing body.

Comment: A number of commenters expressed support for our proposal to rescind the requirement. One commenter appreciated our acknowledgment of the legal issues created by the existing requirement.

Response: We appreciate the commenters' support of our proposed changes.

Comment: Generally, commenters were supportive of our intent to ensure meaningful communication between the governing body and the medical staff. Several commenters supported the provision as written, with one stating that CMS' alternative proposal will ensure a hospital's governing body hears the medical staff perspective on quality of care while leaving appropriate flexibility in the composition of the hospital's governing body.

Response: We appreciate the commenters' support of our proposed changes.

Comment: We received a number of comments expressing concern that the proposed consultation requirement would be overly burdensome, particularly for multi-hospital systems with a single governing body. One commenter stated that for systems with large numbers of hospitals and a single governing board, requiring separate consultations between each medical staff representative and the entire governing board would prove unworkable. One commenter suggested instead allowing for "a committee structure with representatives throughout the system and at a frequency that is flexible." Other commenters suggested various committee-based options and greater flexibility in achieving the objectives of meaningful communication between the governing body and the medical staff.

Response: Our proposal gives governing bodies flexibility to determine the most effective and efficient way to meet the requirement. We believe it allows sufficient flexibility for hospitals to meet this requirement in a manner appropriate to each organization. As written, this provision does not require separate consultations with each leader of each medical staff and does not exclude the possibility of consulting with multiple medical staff leaders simultaneously using some form of committee structure, so long as the direct consultation occurs periodically throughout the fiscal or calendar year and includes discussion of matters related to the quality of

medical care provided to patients of each hospital. Similar to our discussion in the preamble to the May 16, 2012 Final Rule (77 FR 29038), we expect hospital governing bodies, especially a multi-hospital system's single governing body, to carefully consider the unique needs of the patient populations served by its member hospital(s) and their respective medical staffs when determining the number and the type of consultations needed to achieve the necessary communication between the governing body and the medical staff. Furthermore, this proposal does not preclude medical staff membership on the governing body.

Comment: One commenter felt that the proposed provision would not achieve the objective of meaningful communication and several commenters stated that "[w]e do not accept the premise that 'direct consultation,' no matter how frequent or in what form, is an adequate substitution for medical staff representation on a hospital's governing body." One commenter stated that if this proposal is implemented, medical staffs would be unable to comply with § 482.12(a)(5) requiring "that the medical staff is accountable to the governing body for the quality of care provided to patients."

Response: We believe that our proposal will provide for meaningful communication between the governing body and the medical staff while avoiding the complications created by the current requirement. We are confused by the comment that the implementation of this proposed requirement would make it impossible for medical staffs to comply with the current requirement at § 482.12(a)(5) listed above or with § 482.22(b), which requires the medical staff to be "well organized and accountable to the governing body for the quality of the medical care provided to the patients." The finalized requirement merely codifies the requirements applicable to communications regarding the hospital's quality of patient care, which should be occurring regularly between the governing body and the medical staff. We do not see how the addition of

this requirement would make the medical staff *less* accountable to the governing body for the quality of care provided to patients in the hospital. By requiring direct consultation, we believe that the medical staff would be ensured a forum in which its collective voice can be heard regarding patient care. If anything, the requirement holds the governing body accountable to the medical staff for providing that forum through direct consultation.

Comment: Several commenters requested examples of compliance or additional clarification regarding what constitutes "direct consultation."

Response: "Direct consultation" means that the governing body, or a subcommittee thereof, meets with the medical staff leader(s) either face-to-face or via a telecommunications system permitting immediate, synchronous communication.

Comment: One commenter asked if having a member of the medical staff on the governing body would meet the consultation requirement.

Response: As noted earlier, this proposal does not preclude including medical staff on the governing body, as full, non-voting, or ex-officio member(s). However, a hospital would meet the consultation requirement only if the medical staff member serving on the governing body is the same individual responsible for the organization and conduct of the hospital's 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 and the bylaws governing terms and conditions of governing body membership did not allow for substitution of the new medical staff leader (or his or her designee) on the governing body, then the governing body would be expected to engage in direct consultation with the individual newly responsible for the organization and conduct of the medical staff (or

his or her designee). It should be noted that if a hospital chooses to meet the requirement in this manner, there is nothing in the requirements to prohibit the hospital from including other medical staff members on the governing body in addition to the member responsible for the organization and conduct of the medical staff.

After consideration of the comments discussed above, we are finalizing the changes to § 482.12 as proposed.

2. Medical Staff (§ 482.22)

Similar to the issues regarding medical staff representation on the governing body that were discussed in the previous section, we also received a considerable amount of feedback regarding our responses in the May 16, 2012 final rule (77 FR 29061) where we discussed our interpretation of the Medical staff CoP at § 482.22 as requiring that each hospital have its own independent medical staff despite the arguable ambiguity of the regulatory language. After the publication of the May 16, 2012 final rule, it was brought to our attention that, over the years, this apparently ambiguous language might have led some stakeholders to interpret § 482.22 as allowing for separately certified hospitals, as members of a multi-hospital system, to share a unified and integrated medical staff. Therefore, we proposed to amend the introductory paragraph of § 482.22 to require that each hospital must have an organized and individual medical staff, distinct to that individual hospital, which operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients of that individual hospital.

Shortly after publication of the May 2012 final rule, it was also brought to our attention that some of the changes made to the hospital requirements at § 482.22(a), "Medical staff," were not clear. Our intent in revising the provision was to provide the flexibility that hospitals need

under federal law to maximize their medical staff opportunities for all practitioners, but within the regulatory boundaries of their State licensing and scope-of-practice laws. We believe that the greater flexibility for hospitals and medical staffs to enlist the services of non-physician practitioners to carry out the patient care duties for which they are trained and licensed will allow them to meet the needs of their patients most efficiently and effectively.

Section 482.22(a), "Standard: Eligibility and process for appointment to medical staff," currently requires a hospital's medical staff to be composed of doctors of medicine or osteopathy. It also allows for a hospital's medical staff to include other categories of non-physician practitioners determined as eligible for appointment by the governing body, in accordance with State law, including scope-of-practice laws. With the substitution of the term "non-physician practitioners" in the final rule (which replaced the term "other practitioners"), we might have unintentionally given the impression that the requirements now excluded other types of practitioners previously included among those eligible for appointment to the medical staff. In our guidance prior to the issuance of this final rule, we stated that a medical staff could include "other practitioners" such as doctors of dental surgery or of dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors, as those terms are defined and specified as physicians under section 1861(r) of the Act. Because part of § 482.22(a) states that a hospital's medical staff must include "doctors of medicine or osteopathy," other types of physicians, such as those listed above, are inadvertently excluded from the term "medical staff." Similarly, the new term "non-physician practitioner" therefore might also seem to exclude these other types of physicians simply by its use of the modifier, "non-physician," since by the definition described at section 1861(r) of the Act, the practitioners are "physicians," they cannot also be considered to be "non-physicians." Our intention was not to exclude these types of

physicians from the definition described in our regulations. Therefore, we believe it was appropriate to propose revisions to § 482.22(a) to clarify that the medical staff requirements still allow for these types of physicians as well as other types of non-physician practitioners to be eligible for appointment to a hospital's medical staff.

At § 482.22(a), we proposed to revise the current language to require that a hospital's medical staff must be composed of physicians and that it may also include, in accordance with State laws, including scope-of-practice laws, other categories of non-physician practitioners determined as eligible for appointment by the governing body. We indicated that the proposed substitution of the current terms, "doctors of medicine or osteopathy," with the term "physicians," would be consistent with the statutory language. We also proposed to substitute "must include" with "must be composed of" since we believe that this more accurately reflects the fact that hospital medical staffs are predominantly made up of physicians and would also emphasize the vital positions that physicians hold on these medical staffs. We stated that this proposed regulatory language would require that the medical staff be composed of physicians. Finally, we proposed to retain the language allowing for other types of non-physician practitioners (such as Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), Registered Dietitians (RDs), and Doctors of Pharmacy (PharmDs)) to be included on the medical staff since we continue to believe that these practitioners, even though they are not included in the statutory definition of a physician, nevertheless have equally important roles to play on a medical staff and in the quality of medical care provided to patients in the hospital.

We received over 100 comments on our proposed changes to § 482.22 from individuals, national and State professional organizations, accreditation organizations, individual hospitals and multi-hospital systems, and national and State hospital organizations. Regarding the

proposed requirement for a single medical staff for each individual hospital, there was a clear split among commenters with a pronounced difference of opinion on this issue between primarily physicians and their professional organizations on one side and hospitals, multi-hospital systems, an accreditation organization, and hospital organizations on the other. For the most part, physicians and their organizations were supportive of the proposed changes. However, there were some physicians, most clearly those who stated that they had experience with a unified and integrated medical staff for multiple hospitals within a system, who were opposed to our proposed changes. On the other side, hospitals and their organizations, along with accreditation organizations, were opposed to our proposed change to prohibit a unified and integrated medical staff structure for a multi-hospital system made up of separately certified member hospitals.

On the proposed changes to the composition of the medical staff requirements, the comments were mixed though generally supportive of the changes. A number of commenter asked for further clarification of these changes.

Here we respond to specific comments:

Comment: Regarding the proposed changes to the composition of the medical staff, one commenter questioned whether non-physician practitioners and other practitioners (for example, podiatrists, dentists, and oral surgeons) would be granted hospital privileges and be allowed to practice if State law only permitted MDs and DOs to be medical staff members.

Response: The requirement at § 482.22(a) has always allowed hospitals to grant medical staff membership for non-physician practitioners as well as other practitioners who are not MDs/DOs only if such membership is in accordance with State law. Although our expectation is that all practitioners granted privileges are also members of the medical staff, if State law limits the composition of the medical staff to certain categories of practitioners, there is nothing in the

CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for those specific categories of 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. However, CMS has always expected a hospital and its medical staff to exercise oversight, such as credentialing and competency review, of those practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Comment: Several commenters expressed concerned with our referring to practitioners who are not MDs or DOs as "physicians." One commenter stated that CMS was trying to undermine the traditional hospital medical staff leadership model composed solely or primarily of MDs and DOs by replacing that model with one composed largely of non-physician practitioners who are hospital employees.

Response: As we stated above, the changes proposed as well as the current requirements do not require hospitals and their medical staffs to appoint practitioners other than MDs and DOs to their medical staffs. The requirement provides hospitals and medical staffs with an option of medical staff appointment for practitioners who are not MDs or DOs, not a requirement. However, in our attempts in the proposed rule to correct the omission of other categories of physicians (as defined in § 1861(r) of the Act and listed at § 482.12(c)(1)) in this requirement, we believe, based on some of the comments received, we might have further confused the issue of the composition of the medical staff. Therefore, we are finalizing a revision to § 482.22(a) in this rule that we believe will adequately present the required part of this provision and that part which is only optional. We are revising the regulatory language to now state that the "medical staff *must* be composed of *doctors of medicine or osteopathy*," and that 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." [Emphasis added.]

Comment: We received a large number of comments from individual physicians as well as national and State physician organizations that supported our proposed changes to reaffirm and make more explicit the requirement that each hospital to have its own medical staff, specifically those hospitals that are part of a multi-hospital system. These commenters stated they believed that allowing a multi-hospital system to have a unified and integrated medical staff instead of separate medical staffs for each hospital would destroy the concept of medical staff self-governance that is "a basic requirement" for TJC hospital accreditation and which is "mandated by some states." Additionally, there were some comments from individuals as well as hospital leaders that stated that while they support the proposed requirement overall, they believed that there should be some allowance for hospitals within a system to share medical staff bylaws, rules, and regulations.

Conversely, we also received an equally large number of comments from hospitals, multi-hospital systems, national and State hospital organizations, and individual physicians that rejected these same proposed changes. These commenters offered both anecdotal evidence and preliminary research evidence to support their arguments that unified and integrated medical staffs provide the best means for multi-hospital systems to more efficiently standardize evidence-based "best" practices (for example, innovations that have been proven to reduce healthcare-associated infections (HAIs), hospital-acquired conditions (HACs), and readmissions) across member hospitals. A number of commenters also disputed claims that a unified and integrated medical staff structure for multiple hospitals within a system would undermine medical staff

self-governance and pointed out that there is no evidence that the separate-medical-staff-for-each-hospital structure improves the quality of patient care or protects patient safety. A few commenters pointed to several specific benefits that can potentially be derived from a unified and integrated medical staff structure including:

- Increased opportunity to improve peer review processes.
- Improved patient safety through shared credentialing and privileging.
- More efficient sharing of knowledge and innovations among medical staff members.
- Better physician on-call coverage for specialties.
- Consistency with the move toward accountable care organizations and modern care delivery systems.
- More efficient coordination of emergency preparedness and community health planning.

Among the comments supporting unified and integrated medical staffs some stated that they believed that CMS should allow it as an option for hospitals that might not be using such a structure currently. One commenter argued that because the structure of a hospital's medical staff is commonly defined within medical staff bylaws, which must be approved by both the medical staff and the governing body, a multi-hospital governing body cannot unilaterally force the members of its separate hospital medical staffs to accept a single, unified, and integrated medical staff. This commenter stated that the members of the system's separate hospital medical staffs had voted many years ago to structure themselves as a unified medical staff because the majority of medical staff members believed that this was the best way for the system and its medical staffs to "achieve our goals for mutual integration." The commenter further reinforced

the idea that this change was not forced upon the separate medical staffs by stating that the medical staff and its members "were, and remain responsible for their self-governance." The commenter recommended that hospital systems with separately certified hospitals that wish to adopt an integrated medical staff structure should be required to provide for an election or vote on the issue to ensure that the medical staff of each hospital is in agreement. One commenter also noted that unified medical staffs "are self-governing entities that can and do respect the diversity, viewpoints and concerns of medical staff members across the system." Several commenters in support of unified medical staffs pointed out that many unified medical staffs rely on a system of committees made up of representatives from the various hospitals in a system. These commenters argued that while the unified medical staff model allows for more efficient patient care coordination, the committees and member representatives ensure that hospital-specific concerns are voiced, heard, and addressed by the unified medical staff and the governing body.

Other commenters pointed out the significant burden that would be imposed on hospitals already operating under this structure if CMS were to finalize the proposed requirement. They pointed to the significant cost of dismantling the unified medical staffs under which many have been operating for several years in many accredited hospitals, in addition to the burden of having to establish new medical staffs at each such member hospital with new bylaws, rules, regulations, and committee structures. A few commenters also asserted that there might be inconsistency in CMS allowing for a single unified structure for a multi-hospital system's governing body (as we did in the May 12, 2012 final rule), but denying the same flexibility for its medical staff structure.

Finally, there were several commenters who stated that they while they disagreed with the proposed clarifications, and believed that a multi-hospital system should be allowed to have a unified and integrated medical staff, they believed that there should be specific parameters limiting how many member hospitals could possibly share a unified medical staff within a system. Commenters suggested establishing a specific number of hospitals or limiting the geographic range by state or metropolitan statistical area.

Response: We appreciate all of the comments received on this issue. After carefully considering all of the arguments for and against allowing a multi-hospital system to use a unified and integrated medical staff structure for its member hospitals, we believe that it is in the best interest of hospitals, medical staff members, and patients to modify our proposed prohibition on the use of a unified and integrated medical staff for a multi-hospital system and its member hospitals so as to enable the medical staff of each hospital to voluntarily integrate itself into a larger system medical staff.

The fact that many hospital systems have been using a unified medical staff model for a number of years, without evidence showing that such a system is detrimental to patients or decreases the quality of care delivered, was a major factor in our decision to allow hospitals and their respective medical staffs the flexibility to decide which medical staff framework works best for their particular situations. The arguments against allowing this flexibility through the CoPs did not provide any evidence that having a single and separate medical staff for each hospital within a system was inherently superior to the unified and integrated model. We weighed this argument against the comments from the physician leaders and members of unified and integrated medical staffs who provided testimony and anecdotal evidence for the benefits of this type of structure. Additionally, we considered preliminary evidence that appears to show that

hospitals using a unified medical staff might be achieving some success in reducing HACs, HAIs, and readmissions, and in improving patient safety and outcomes. One commenter, writing on behalf of a multi-hospital system that the commenter references as the largest in their State, stated that "we believe the concept of a single medical staff has substantially contributed to our success as an integrated delivery system and has accelerated our quality, safety and efficiency performance." The commenter cited the system's achievements, which they believe are a result of this single and integrated medical staff model: core measures in the top quartile with excellent value-based purchasing scores according to CMS; lower in-hospital mortality rates that are statistically significant, that is, 17 percent lower than expected; lower hospital readmission rates that are statistically significant, that is, 15 percent lower than expected; and the second lowest congestive heart failure readmission rate in the nation, according to published CMS data. We agree that it appears to be evident that a unified system medical staff would usually be better suited to standardizing best practices and implementing quality improvements than would the more fragmented structure of separate medical staffs.

While we do not agree with comments that stated that a unified and integrated medical staff would destroy medical staff self-governance, we appreciate that added flexibility allowing a multi-hospital unified medical staff might conceivably be implemented in a manner that fails to achieve the desired benefits. We also received comments suggesting that if flexibility were permitted, CMS should place parameters or limitations on the use of a unified medical staff. We believe that the specifics should be left up to the medical staffs and governing bodies to determine, but agree that basic parameters are advisable to address the concerns of commenters and ensure due consideration of the unique aspects of each involved hospital (such as requiring

that the hospitals have considered the extent to which a medical staff can be shared among its member hospitals as defined in hospital and medical staff policy, by-laws, and protocols).

Therefore, we are revising the proposed requirement and finalizing it here by retaining the original and current language of the condition statement, which states that the hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. We believe that this will provide more flexibility for each hospital and medical staff to determine the medical staff framework which works best for their situation (for example, whether that decision is for a separate medical staff for each hospital or a unified and integrated medical staff for multiple hospitals with a system). We are also revising this CoP (at § 482.22(b)) to include new provisions that will hold a hospital responsible for showing that it actively addresses its use of a unified and integrated staff model. Under the provisions of this final rule, the unified medical staff would still be composed of medical staff members from each hospital in the system and each member would be eligible to take on a leadership role on the various committees and subcommittees just as he or she would if he or she were part of a separate medical staff. Further, a medical staff and a governing body would still need to work closely together, with the medical staff responsible for the quality of care provided and accountable to the governing body. Neither the governing body nor the medical staff may impose its will unilaterally. They are dependent on each other for the hospital's success. For medical staffs and multi-hospital systems that choose to exercise the flexibility provided by this CoP (to use a unified and integrated medical staff, after determining that such a decision is in accordance with all applicable State and local laws), these new provisions are aimed at ensuring that--

(1) 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 according to provisions included in the medical staff bylaws or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;

(2) 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;

(3) The unified and integrated medical staff is established in a manner that takes into account each hospital's unique circumstances, and any significant differences in patient populations (such as low income or minority populations, rural populations, etc.) and services offered in each hospital (such as emergency services, psychiatric services, pediatric care, long term acute care, organ transplant services, dialysis, etc.); and

(4) The unified and integrated medical staff gives due consideration to the needs and concerns of members of the medical staff, regardless of practice or location, and the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

Finally, we note that some commenters argued in support of a unified medical staff by pointing to our previous position permitting a single governing body for hospitals within a system. We believe that the CoPs pertaining to the governing body and medical staff are unique in their focus on governance processes. We are taking this opportunity to emphasize that permitting use of a system governing body or medical staff must not be construed as implying that compliance with any other hospital CoPs may also be demonstrated at the system (multi-hospital) level. Each separately participating hospital is required to demonstrate its compliance with all other hospital CoPs in order to participate in Medicare. Although there can be system approaches in many of these areas (such as infection control or quality assessment/performance improvement programs), each individual hospital must demonstrate that it fulfills the applicable CoP requirements.

3. Food and Dietetic Services (§ 482.28)

We proposed to revise the hospital requirements at § 482.28(b), "Food and dietetic services," which currently requires that a therapeutic diet must be prescribed only by the practitioner or practitioners responsible for the care of the patient.

The Interpretive Guidelines (IGs) for this requirement, which are contained in the State Operations Manual (SOM) for surveyors, further state that "[in] accordance with State law and hospital policy, a dietitian may assess a patient's nutritional needs and provide recommendations or consultations for patients, but the patient's diet must be prescribed by the practitioner responsible for the patient's care." State survey agencies have applied this requirement to mean that registered dietitians or other clinically qualified nutrition professionals (RDs) cannot be granted privileges by the hospital to order patient diets (or to order necessary laboratory tests to monitor the effectiveness of dietary plans and orders, or to make subsequent modifications to