

[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

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.