§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.

10) [the governing body must..] Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital’s medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital. For a multi-hospital system using a single governing body, the single multihospital 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).

§482.12(a) Standard: Medical Staff

The governing body must ensure the medical staff requirements are met.

§482.12(a)(1) [The governing body must:] 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 medical staff must, at a minimum, be composed of physicians who are doctors of medicine or doctors of osteopathy. In addition, the medical staff may include other practitioners included in the definition in Section 1861(r) of the Social Security Act of a physician:

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

In all cases, the practitioners 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 to determine whether other types of practitioners included in the definition of a physician are eligible for appointment to the medical staff.

Furthermore, the governing body has the authority, in accordance with State law, to appoint some types of non-physician practitioners, such as nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives, to the medical staff. Practitioners, both physicians and non-physicians, may be granted privileges to practice at the hospital by the governing body for practice activities authorized within their State scope of practice without being appointed a member of the medical staff.

§482.12(a)(2) [The governing body must:] Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

Interpretive Guidelines §482.12(a)(2)

The governing body determines whether to grant, deny, continue, revise, discontinue, limit, or revoke specified privileges, including medical staff membership, for a specific practitioner after considering the recommendation of the medical staff. In all instances, the governing body’s determination must be consistent with established hospital medical staff criteria, as well as with State and Federal law and regulations. Only the hospital’s governing body has the authority to grant a practitioner privileges to provide care in the hospital.

§482.12(a)(3) [The governing body must:] Assure that the medical staff has bylaws;

Interpretive Guidelines §482.12(a)(3)

The governing body must assure that the medical staff has bylaws and that those bylaws comply with State and Federal law and the requirements of the Medicare hospital Conditions of Participation.

§482.12(a)(4) [The governing body must:] Approve medical staff bylaws and other medical staff rules and regulations;

Interpretive Guidelines §482.12(a)(4)

The governing body decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body before they are considered effective.

§482.12(a)(5) [The governing body must:] Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;
**Interpretive Guidelines §482.12(a)(5)**

The governing body must ensure that the medical staff as a group is accountable to the governing body for the quality of care provided to patients. The governing body is responsible for the conduct of the hospital and this conduct includes the quality of care provided to patients.

All hospital patients must be under the care of a practitioner who meets the criteria of 42 CFR 482.12(c)(1) and who has been granted medical staff privileges, or under the care of a practitioner who is directly under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner who has been granted privileges in accordance with the criteria established by the governing body, and who is working within the scope of those granted privileges.

**§482.12(a)(6)** [The governing body must:] Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

**Interpretive Guidelines §482.12(a)(6)**

The governing body must assure that the medical staff bylaws describe the privileging process to be used by the hospital. The process articulated in the medical staff bylaws, rules, or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

- Individual character;
- Individual competence;
- Individual training;
- Individual experience; and
- Individual judgment.

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.

**§482.12(a)(7)** [The governing body must:] Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

**Interpretive Guidelines §482.12(a)(7)**

In making a judgment on medical staff membership, a hospital may not rely solely on the fact that a MD/DO is, or is not, board-certified. This does not mean that a hospital is prohibited from requiring board certification when considering a
MD/DO for medical staff membership, but only that such certification must not be the only factor that the hospital considers. In addition to matters of board certification, a hospital must also consider other criteria such as training, character, competence and judgment. After analysis of all of the criteria, if all criteria are met except for board certification, the hospital has the discretion to decide not to select that individual to the medical staff.

§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 is responsible for the quality of medical care provided to patients by the hospital.

Interpretive Guidelines §482.22(a):

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

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

In all cases the practitioners 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 whether other types of practitioners included in the definition of a physician are eligible for appointment to the medical staff. Furthermore, the governing body has the authority, in accordance with State law, to appoint some types of non-physician practitioners, such as nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives, to the medical staff. Practitioners, both physicians and non-physicians, may be granted privileges to practice at the hospital by the governing body for practice activities authorized within their State scope of practice without being appointed a member of the medical staff.

482.22(a) Standard: Composition of the Medical Staff
The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

§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; (ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital; (iii) The unified and integrated medical staff is established in a manner that takes into account each member hospital’s unique circumstances and any significant differences in patient populations and services offered in each hospital; and (iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

§482.22(a)(1) The medical staff must periodically conduct appraisals of its members.

Interpretive Guidelines §482.22(a)(1)

The medical staff must at regular intervals appraise the qualifications of all practitioners appointed to the medical staff/granted medical staff privileges. In the absence of a State law that establishes a timeframe for periodic reappraisal, a hospital’s medical staff must conduct a periodic appraisal of each practitioner. CMS recommends that an appraisal be conducted at least every 24 months for each practitioner.
The purpose of the appraisal is for the medical staff to determine the suitability of continuing the medical staff membership or privileges of each individual practitioner, to determine if that individual practitioner’s membership or privileges should be continued, discontinued, revised, or otherwise changed. The medical staff appraisal procedures must evaluate each individual practitioner’s qualifications and demonstrated competencies to perform each task or activity within the applicable scope of practice or privileges for that type of practitioner for which he/she has been granted privileges. Components of practitioner qualifications and demonstrated competencies would include at least: current work practice, special training, quality of specific work, patient outcomes, education, maintenance of continuing education, adherence to medical staff rules, certifications, appropriate licensure, and currency of compliance with licensure requirements.

In addition to the periodic appraisal of members, any Procedure/task/activity/privilege requested by a practitioner that goes beyond the specified list of privileges for that particular category of practitioner requires an appraisal by the medical staff and approval by the governing body. The appraisal must consider evidence of qualifications and competencies specific to the nature of the request. It must also consider whether the activity/task/procedure is one that the hospital can support when it is conducted within the hospital. Privileges cannot be granted for tasks/procedures/activities that are not conducted within the hospital, regardless of the individual practitioner’s ability to perform them.

After the medical staff conducts its reappraisal of individual members, the medical staff makes recommendations to the governing body to continue, revise, discontinue, limit, or revoke some or all of the practitioner’s privileges, and the governing body takes final appropriate action.

A separate credentials file must be maintained for each medical staff member. The hospital must ensure that the practitioner and appropriate hospital patient care areas/departments are informed of the privileges granted to the practitioner, as well as of any revisions or revocations of the practitioner’s privileges. Furthermore, whenever a practitioner’s privileges are limited, revoked, or in any way constrained, the hospital must, in accordance with State and/or Federal laws or regulations, report those constraints to the appropriate State and Federal authorities, registries, and/or data bases, such as the National Practitioner Data Bank.

§482.22(a)(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

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.

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.

§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 an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

Interpretive Guidelines §482.22(b)

The medical staff must be accountable to the hospital’s governing body for the quality of medical care provided to the patients. The organization of the medical staff must comply with these requirements.
§482.22(c) Standard: Medical Staff Bylaws

The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

Interpretive Guidelines §482.22(c)

The medical staff must regulate itself by bylaws that are consistent with the requirements of this and other CoPs that mention medical staff bylaws, as well as State laws. The bylaws must be enforced and revised as necessary.

§482.22(c)(1) [The bylaws must] Be approved by the governing body.

Interpretive Guidelines §482.22(c)(1)

Medical staff bylaws and any revisions of those bylaws must be submitted to the governing body for approval. The governing body has the authority to approve or disapprove bylaws suggested by the medical staff. The bylaws and any revisions must be approved by the governing body before they are considered effective.

§482.22(c)(2) [The bylaws must] Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

Interpretive Guidelines §482.22(c)(2)

The medical staff bylaws must state the duties and scope of medical staff privileges each category of practitioner may be granted. Specific privileges for each category must clearly and completely list the specific privileges or limitations for that category of practitioner. The specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support.

Although the medical staff bylaws must address the duties and scope for each category of practitioner, this does not mean that each individual practitioner within the category may automatically be granted the full range of privileges. It cannot be assumed that every practitioner can perform every task/activity/privilege that is specified for the applicable category of practitioner. The individual practitioner’s ability to perform each task/activity/privilege must be individually assessed.

§482.22(c)(3) [The bylaws must] Describe the organization of the medical staff.

Interpretive Guidelines §482.22(c)(3)
The medical staff bylaws must describe the organizational structure of the medical staff, and lay out the rules and regulations of the medical staff to make clear what are acceptable standards of patient care for all diagnostic, medical, surgical, and rehabilitative services.

§482.22(c)(4) [The bylaws must] Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

Interpretive Guidelines §482.22(c)(4)

The medical staff bylaws must describe the qualifications to be met by a candidate for medical staff membership/privileges in order for the medical staff to recommend the candidate be approved by the governing body. The bylaws must describe the privileging process to be used in the hospital. The process articulated in the medical staff bylaws must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

- Individual character;
- Individual competence;
- Individual training;
- Individual experience; and
- Individual judgment.

The medical staff may not rely solely on the fact that a MD/DO is, or is not, board-certified in making a judgment on medical staff membership. This does not mean that the medical staff is prohibited from requiring board certification when considering a MD/DO for medical staff membership; only that such certification is not the only factor that the hospital considers. After analysis of all of the criteria, if all criteria are met except for board certification, the medical staff has the discretion to not recommend that individual for medical staff membership/privileges.

The bylaws must apply equally to all practitioners in each professional category of practitioners.

The medical staff then recommends individual candidates that meet those requirements to the governing body for appointment to the medical staff.

482.22(c)(5) [The bylaws must] Include a requirement that –

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and
documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

**Interpretive Guidelines §482.22(c)(5)(i)**

The purpose of a medical history and physical examination (H&P) is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient.

The Medical Staff bylaws must include a requirement that an H&P be completed and documented for each patient no more than 30 days prior to or 24 hours after hospital admission or registration, but prior to surgery or a procedure requiring anesthesia services. The H&P may be handwritten or transcribed, but always must be placed within the patient’s medical record within 24 hours of admission or registration, or prior to surgery or a procedure requiring anesthesia services, whichever comes first.

An H&P is required prior to surgery and prior to procedures requiring anesthesia services, regardless of whether care is being provided on an inpatient or outpatient basis. (71 FR 68676) An H&P that is completed within 24 hours of the patient’s admission or registration, but after the surgical procedure, procedure requiring anesthesia, or other procedure requiring an H&P would not be in compliance with this requirement.

The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Section 1861(r) defines a physician as a:
- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry; or a
- Chiropractor.

In all cases the practitioners 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 attaches further limitations as to the type of hospital services for which a practitioner is considered to be a “physician.”
Other qualified licensed individuals are those licensed practitioners who are authorized in accordance with their State scope of practice laws or regulations to perform an H&P and who are also formally authorized by the hospital to conduct an H&P. Other qualified licensed practitioners could include nurse practitioners and physician assistants.

More than one qualified practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents. (71 FR 68675)

A hospital may adopt a policy allowing submission of an H&P prior to the patient’s hospital admission or registration by a physician who may not be a member of the hospital's medical staff or who does not have admitting privileges at that hospital, or by a qualified licensed individual who does not practice at that hospital but is acting within his/her scope of practice under State law or regulations. Generally, this occurs where the H&P is completed in advance by the patient’s primary care practitioner. (71 FR 68675)

When the H&P is conducted within 30 days before admission or registration, an update must be completed and documented by a licensed practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P.

482.22(c)(5) – The Bylaws must include a requirement that

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient’s condition, must be completed and documented by a licensed practitioner who is credentialed and privileged by the hospital’s medical staff to perform an H&P. In all cases, the update must take place prior to surgery or a procedure requiring anesthesia services. The update note must document an examination for any
changes in the patient's condition since the patient's H&P was performed that might be significant for the planned course of treatment. The physician or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient’s condition and co-morbidities, if any, in relation to the patient’s planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient’s medical record.

If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed (71 FR 68676). Any changes in the patient’s condition must be documented by the practitioner in the update note and placed in the patient’s medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services. Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

§482.22(c)(6) [The bylaws must] Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

Interpretive Guidelines §482.22(c)(6)

All patient care is provided by or in accordance with the orders of a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges. Privileges are granted by the hospital's governing body to individual practitioners based on the medical staff’s review of that individual practitioner’s qualifications and the medical staff’s recommendations for that individual practitioner to the governing body.

§482.22(d) Standard: Autopsies

The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

§482.51(a)(4) - Surgical Privileges
Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

**Interpretive Guidelines §482.51(a)(4)**

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner’s specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must also be retained in these areas/locations.

The hospital must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner’s training, education, experience, and demonstrated competence as established by the hospital’s QAPI program, credentialing process, the practitioner’s adherence to hospital policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The hospital must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DO, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same OR, in line of sight of the practitioner being supervised) be delineated in that practitioner’s surgical privileges and included on the surgical roster.

If the hospital utilizes RN First Assistants, surgical PA, or other non-MD/DO surgical assistants, the hospital must establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner’s compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations. This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO.
When practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term “supervision” would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted specific surgical privileges by the governing body in accordance with those criteria, and who is working within the scope of those granted and documented privileges.