(b) **Standard: Program data.** (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital’s Quality Improvement Organization.
(2) The hospital must use the data collected to—
   (i) Monitor the effectiveness and safety of services and quality of care; and
   (ii) Identify opportunities for improvement and changes that will lead to improvement.
(3) The frequency and detail of data collection must be specified by the hospital’s governing body.

(c) **Standard: Program activities.** (1) The hospital must set priorities for its performance improvement activities that—
   (i) Focus on high-risk, high-volume, or problem-prone areas;
   (ii) Consider the incidence, prevalence, and severity of problems in those areas; and
   (iii) Affect health outcomes, patient safety, and quality of care.
(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.
(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) **Standard: Performance improvement projects.** As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.
(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.
(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.
(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.
(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) **Standard: Executive responsibilities.** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:
(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.
(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.
(3) That clear expectations for safety are established.
(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital’s performance and reducing risk to patients.
(5) That the determination of the number of distinct improvement projects is conducted annually.

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§ 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.

(a) **Standard: Eligibility and process for appointment to medical staff.** The medical staff must include doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of non-physician practitioners determined as eligible for appointment by the governing body.
(1) The medical staff must periodically conduct appraisals of its members.

(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 these 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.

(3) When telemedicine services are furnished to the hospital’s patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital’s governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician’s or practitioner’s privileges at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients and all complaints the hospital has received about the distant-site physician or practitioner.

(4) When telemedicine services are furnished to the hospital’s patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital’s governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with §482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital’s governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards at §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician’s or practitioner’s privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in
(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients, and all complaints the hospital has received about the distant-site physician or practitioner.

(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 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.

(c) Standard: Medical staff bylaws. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) 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.

(5) 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.

(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 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.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(6) and (a)(9), and §482.22(a)(3) and (a)(4).

(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.


§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) Standard: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient’s needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) Standard: Preparation and administration of drugs. (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient’s care as specified under §482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(ii) Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(3) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law.