§ 482.1

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Source: 51 FR 22042, June 17, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 482.1 Basis and scope.

(a) Statutory basis. (1) Section 1861(e) of the Act provides that—

(i) Hospitals participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.

(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary.

(3) Sections 1861(k) and 1902(a)(30) of the Act provide that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.

(4) Section 1883 of the Act sets forth the requirements for hospitals that provide long term care under an agreement with the Secretary.

(5) Section 1905(a) of the Act provides that “medical assistance” (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§ 440.10 and 440.165 of this chapter.).

(b) Scope. Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

[51 FR 22042, June 17, 1986, as amended at 60 FR 50442, Sept. 29, 1995]

§ 482.2 Provision of emergency services by nonparticipating hospitals.

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if—

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e) (1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.


Subpart B—Administration

§ 482.11 Condition of participation: Compliance with Federal, State and local laws.

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be—

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.
§ 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. 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.

(a) Standard: Medical staff. The governing body must:
(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;
(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;
(3) Assure that the medical staff has bylaws;
(4) Approve medical staff bylaws and other medical staff rules and regulations;
(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;
(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and
(7) Ensure that under no circumstances is the appointment of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.

(b) Standard: Chief executive officer. The governing body must appoint a chief executive officer who is responsible for managing the hospital.

(c) Standard: Care of patients. In accordance with hospital policy, the governing body must ensure that the following requirements are met:
(1) Every Medicare patient is under the care of:
   (i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State’s regulatory mechanism.);
   (ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;
   (iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;
   (iv) A doctor of optometry who is legally authorized to practice optometry.
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by the State in which he or she practices:

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and

(vi) A clinical psychologist as defined in § 410.71 of this chapter, but only with respect to clinical psychologist services as defined in § 410.71 of this chapter and only to the extent permitted by State law.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—

(i) is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

(d) Standard: Institutional plan and budget. The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility’s patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared—
(i) Under the direction of the governing body; and
(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) Standard: Contracted services. The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) Standard: Emergency services. (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

§482.13 Condition of participation: Patient’s rights.

A hospital must protect and promote each patient’s rights.

(a) Standard: Notice of rights—(1) A hospital must inform each patient, or when appropriate, the patient’s representative (as allowed under State law), of the patient’s rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital’s governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient’s written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) Standard: Exercise of rights. (1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient’s rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who
provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) **Standard: Privacy and safety.**

(1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) **Standard: Confidentiality of patient records.**

(1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) **Standard: Restraint or seclusion.**

All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) **Definitions.**

(i) A restraint is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient’s behavior or restrict the patient’s freedom of movement and is not a standard treatment or dosage for the patient’s condition.

(ii) A seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient and a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient’s plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

(6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(8) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical
safety of the patient, a staff member,
or others may only be renewed in ac-
cordance with the following limits for
up to a total of 24 hours:
(A) 4 hours for adults 18 years of age
or older;
(B) 2 hours for children and adoles-
cents 9 to 17 years of age; or
(C) 1 hour for children under 9 years
of age; and
(ii) After 24 hours, before writing a
new order for the use of restraint or se-
clusion for the management of violent
or self-destructive behavior, a physi-
cian or other licensed independent
practitioner who is responsible for the
care of the patient as specified under
§482.12(c) of this part and authorized to
order restraint or seclusion by hospital
policy in accordance with State law
must see and assess the patient.
(iii) Each order for restraint used to
ensure the physical safety of the non-
violent or non-self-destructive patient
may be renewed as authorized by hos-
pital policy.
(9) Restraint or seclusion must be
discontinued at the earliest possible
time, regardless of the length of time
identified in the order.
(10) The condition of the patient who
is restrained or secluded must be mon-
tored by a physician, other licensed
independent practitioner or trained
staff that have completed the training
criteria specified in paragraph (f) of
this section at an interval determined
by hospital policy.
(11) Physician and other licensed
independent practitioner training re-
quirements must be specified in hos-
pital policy. At a minimum, physicians
and other licensed independent practi-
tioners authorized to order restraint or
seclusion by hospital policy in accord-
ance with State law must have a work-
ing knowledge of hospital policy re-
garding the use of restraint or seclu-
sion.
(12) When restraint or seclusion is
used for the management of violent or
self-destructive behavior that jeopard-
izes the immediate physical safety of
the patient, a staff member, or others,
the patient must be seen face-to-face
within 1 hour after the initiation of the
intervention—
(i) By a—
(A) Physician or other licensed inde-
pendent practitioner; or
(B) Registered nurse or physician as-
sistant who has been trained in accord-
ance with the requirements specified in
paragraph (f) of this section.
(ii) To evaluate—
(A) The patient’s immediate situ-
ation;
(B) The patient’s reaction to the
intervention;
(C) The patient’s medical and behav-
ioral condition; and
(D) The need to continue or termi-
nate the restraint or seclusion.
(13) States are free to have require-
ments by statute or regulation that are
more restrictive than those contained
in paragraph (e)(12)(i) of this section.
(14) If the face-to-face evaluation
specified in paragraph (e)(12) of this
section is conducted by a trained reg-
istered nurse or physician assistant,
the trained registered nurse or physi-
cian assistant must consult the attend-
ing physician or other licensed inde-
pendent practitioner who is responsible
for the care of the patient as specified
under §482.12(c) as soon as possible
after the completion of the 1-hour face-
to-face evaluation.
(15) All requirements specified under
this paragraph are applicable to the si-
multaneous use of restraint and seclu-
sion. Simultaneous restraint and seclu-
sion use is only permitted if the pa-
tient is continually monitored—
(i) Face-to-face by an assigned,
trained staff member; or
(ii) By trained staff using both video
and audio equipment. This monitoring
must be in close proximity to the pa-
tient.
(16) When restraint or seclusion is
used, there must be documentation in
the patient’s medical record of the fol-
lowing:
(i) The 1-hour face-to-face medical
and behavioral evaluation if restraint
or seclusion is used to manage violent
or self-destructive behavior;
(ii) A description of the patient’s be-
havior and the intervention used;
(iii) Alternatives or other less re-
strictive interventions attempted (as
applicable);
(iv) The patient’s condition or symp-
tom(s) that warranted the use of the
restraint or seclusion; and
(v) The patient’s response to the intervention(s) used, including the rationale for continued use of the intervention.

(f) Standard: Restraint or seclusion: Staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) Training intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;
(ii) As part of orientation; and
(iii) Subsequently on a periodic basis consistent with hospital policy.

(2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.
(ii) The use of nonphysical intervention skills.
(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient’s medical, or behavioral status or condition.
(iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.
(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.
(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients’ behaviors.

(4) Training documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) Standard: Death reporting requirements: Hospitals must report deaths associated with the use of seclusion or restraint.

(1) The hospital must report the following information to CMS:

(i) Each death that occurs while a patient is in restraint or seclusion.
(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient’s death. “Reasonable to assume” in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient’s death.

(3) Staff must document in the patient’s medical record the date and time the death was reported to CMS.

(h) Standard: Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of
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§ 482.21  Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital’s governing body must ensure that the program reflects the complexity of the hospital’s organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) Standard: Program scope. (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(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...